English

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 use 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

The Prosthetic Screws, as part of the Metal Abutment devices, are intended to aid in the treatment of 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 (maxilla and mandible respectively) as part of a one- or two-stage surgical procedure.

Prosthetic Screws meet the intended use of the Metal Abutment devices and aid in the successful treatment of edentulousness by securely fixing an abutment or framework to an endosseous dental implant or abutment.

The Metal Abutments devices allow for immediate restoration placement (i.e., immediate loading) in all indications, except in single tooth situations where the implant placed is shorter than 8mm or in soft bone (type IV) where implant stability may be difficult to obtain. As such, the devices allow for immediate or delayed prosthetic restoration based on the user's evaluation of the patient's eligibility.

The Metal Abutments system constituents are classified as medical devices and are intended for single use on a single patient.

Indications for use

The Southern Implants Metal Abutment devices (including prosthetic screws) are indicated for use in cases of partial or full edentulousness, congenital tooth loss, existing removable dentures or failing/problematic natural dentition in patients who are eligible for placement of one or more dental implants or require revision/replacement of previous dental restorations.

Intended user

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

Intended environment

The devices are intended to be used in a dental laboratory for the manufacture of the restoration and in a clinical environment such as an operating theatre or a dentist consultation room.

Intended patient population

The intended patient population for the device is not dissimilar to that of dental implant therapy.

The intended patient population for implant therapy is partially or fully edentulous patients requiring prosthetic dental restoration in the upper or lower jaw. Restorations may comprise single teeth, partial or full bridges and are fixed restorations.

Additionally, the intended patient population includes those eligible for tissue-supported removable dentures and those who have previously received dental implant therapy.

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. Table A summarises the screws available for each Southern range and the recommended torque values of the Southern screws.

Table A – Torque Tables for Southern Screws

Screw Type	External Hex Screws						
	1.22 Hex	Quad	Slotted	Unigrip	Torx	Torque	Head Diameter
2 Series (M2)	TSH2 TSHZ2 BSH2*	GSQ2 GSQZ2	TSS2 TSSZ2 GSS2 GSSZ2 BSS2*	TSU2 TSUZ2 GSU2 GSUZ2		32-40 Ncm (NOTE: screw TORQUE with PEEK Prosthetics for < Ø4.0 mm implant interfaces: 15 Ncm ≥ Ø4.0 mm implant interfaces: 20 Ncm)	2.70 mm
3 Series (M2)	TSH3 TSHZ3 BSH3*	GSQ3 GSQZ3	TSS3 TSSZ3 GSS3 GSSZ3 BSS3*	TSU3 TSUZ3 GSU3 GSUZ3	TSTZ5-ASC		2.40 mm
INPI (M1.6)	TSH16 BSH16*					32 Ncm	2.40 mm
Piccolo (M1.6)	TS-P-16 BS-P-16*				TS-P-16-ASC (Head Diameter – 2.20 mm)	25-32 Ncm (NOTE: screw TORQUE with PEEK Prosthetics for < Ø4.0 mm implant interfaces: 15 Ncm)	2.15 mm

Screw Type	DC (Deep Conical) Screws			
	1.22 Hex	Torx	Torque	Head Diameter
Standard Screws (M2)	TS-DC5-20 BS-DC5-20*	TS-DC5-ASC	32 Ncm (NOTE: screw TORQUE with PEEK Prosthetics DC5 interface: 20 Ncm)	2.35 mm
Standard Screws (M1.6)	TS-DC4-16 BS-DC4-16*	TS-DC4-ASC (Head Diameter – 2.30 mm)	30 Ncm (NOTE: screw TORQUE with PEEK Prosthetics DC4 interface: 20 Ncm)	2.35 mm
Standard Screws (M1.4)	TS-DC3-14 BS-DC3-14*	TS-DC3-ASC	20 Ncm (NOTE: screw TORQUE with PEEK Prosthetics DC5 interface: 15 Ncm)	2.10 mm
Passive Abutment Screws (M2)	PA-DC5-20T PA-DC5-20B* (anodised purple)		32 Ncm	2.80 mm
Passive Abutment Screws (M1.6)	PA-DC4-16T PA-DC4-16B* (anodised blue)		30 Ncm	2.40 mm
Passive Abutment Screws (M1.4)	PA-DC3-14T PA-DC3-14B* (anodised yellow)		20 Ncm	2.20 mm

Screw Type	Internal Hex (M-series and PROVATA®) Screws				
	1.27 Hex	Quad	Torx	Torque	Head Diameter
Standard Screws (M1.8)	TS-Z-18 BS-Z-18*	GS-Q-18	TS-Z-18-ASC (Head Diameter – 2.30 mm)	32 Ncm (NOTE: screw TORQUE with PEEK Prosthetics: 15 Ncm)	2.25 mm
Standard Screws (M1.6)	TS-Z-16 BS-Z-16*		TS-Z-16-ASC (Head Diameter – 2.20 mm)		2.25 mm
Passive Abutment Screws (M1.8)	PA-M-18T PA-M-18B*	PA-Q-18G			2.60 mm
Passive Abutment Screws (M1.6)	PA-M-16T PA-M-16B*				2.60 mm

Screw Type	SP1 (Single Platform) Screws			
	1.22 Hex	Torx	Torque	Head Diameter
Standard Screws (M1.6)	TS-SP-16 BS-SP-16*	TS-SP-ASC (Head Diameter – 2.20 mm)	32 Ncm	2.00 mm
Passive Abutment Screws (M1.6)	PA-SP-16T PA-SP-16B*			2.40 mm

Screw Type	IT (Internal Octagon) Screws		
	Torx	Torque	Head Diameter
Standard Screws (M2)	TSIT2 GSIT2 BSIT2*	32-40 Ncm	2.70 mm
Passive Abutment Screws (M2)	TS-IT-PA BS-IT-PA*		

Screw Type	TRI-NEX Screws			
	Unigrip	Torx	Torque	Head Diameter
Standard Screws (M2)	TS-L-20 TS-L-20C (coated) GS-L-20 BS-L-20*	TS-L-20-ASC	32-40 Ncm (NOTE: screw TORQUE with PEEK Prosthetics: 20 Ncm)	2.50 mm
Standard Screws (M1.8)	TS-L-18 TS-L-18C (coated) GS-L-18 BS-L-18*	TS-L-18-ASC	32 Ncm (NOTE: screw TORQUE with PEEK Prosthetics: 15 Ncm)	2.50 mm
Passive Abutment Screws (M2)	PA-L-20 PA-L-20G PA-L-20B*		32-40 Ncm	2.70 mm
Passive Abutment Screws (M1.8)	PA-L-18 PA-L-18G PA-L-18B*		32 Ncm	2.70 mm

Screw Type	Compact Conical Abutment Screws					
	1.22 Hex	Slotted	Unigrip	Torx	Torque	Head Diameter
Abutment Level Screws	TSH1 GSH1 BSH1*	TSS1 GSS1 BSS1*	TSU1 GSU1	TST1-ASC (Head Diameter – 2.30 mm)	10-15 Ncm (NOTE: screw TORQUE with PEEK Prosthetics: 15 Ncm)	2.25 mm

Screw Type	Angled Compact Conical Abutment Screws				
	1.22 Hex	Slotted	Unigrip	Torque	Head Diameter
Series 9 and 9Z (M2)		GSS9	TSU9 GSU9 TSUZ9 GSUZ9	20 Ncm	2.50 mm
TRI-NEX (M2)			TU-MCL-20C (coated) GU-MCL-20		2.45 mm
External Hex (M2)			TS-EX-MC		2.38 mm
Internal Hex (M-series and PROVATA®) (M1.8)	TS-Z-MC-18			32 Ncm	2.20 mm
TRI-NEX (M1.8)			TU-MCL-18C (coated) GU-MCL-18	20 Ncm	2.25 mm
Internal Hex (M-series and PROVATA®) (M1.6)	TS-Z-MC-16			32 Ncm	2.20 mm
DC (Deep Conical) (M1.6)	TS-DC4-MC			30 Ncm	2.00 mm
DC (Deep Conical) (M1.4)	TS-DC3-MC			20 Ncm	2.00 mm
SP1 (Single Platform) (M1.6)	TS-SP-MC			20 Ncm	2.00 mm

Screw Type	Procera System		
	Unigrip	Torque	Head Diameter
Standard Screws (M2)	TSP2 TSP2C (coated)	32-40 Ncm	2.50 mm

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 for Laboratory Use Only - Torque values do not apply.*

See CAT-8057 for information on which driver is used with Southern Implants' variety of implant systems.

Clinical benefits

The clinical benefits of prosthetic screws are not dissimilar to that of dental implant therapy as a whole, in which patients can expect to have their missing teeth replaced and/or crowns restored.

Clinical benefits of dental implant therapy include improved chewing function, speech, aesthetics, and patient psychological wellbeing.

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

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

Potential side effects and temporary symptoms: pain, swelling, phonetic difficulties and gingival inflammation. More persistent symptoms: the risks and complications with implants include, but are not limited to: (1) allergic reaction(s) to implant and/or abutment material; (2) breakage of the implant and/or abutment; (3) loosening of the abutment screw and/or retaining screw; (4) infection requiring revision of the dental implant; (5) nerve damage that could cause permanent weakness, numbness, or pain; (6) histologic responses possibly involving macrophages and/or fibroblasts; (7) formation of fat emboli; (8) loosening of the implant requiring revision surgery; (9) perforation of the maxillary sinus; (10) perforation of the labial and lingual plates and (11) bone loss possibly resulting in revision or removal.

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.

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), gold alloy, brass (for laboratory screws only)

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 2 W/kg for head landmark, 1 W/kg whole body (for landmarks within 30 cm of the implant) or 2 W/kg whole body (for landmarks more than 30 cm from the implant), and appropriate partial body SAR for other landmarks). For imaging landmarks above the thorax, 15 min of scanning at normal operating mode for landmarks greater than 30 cm from the implant with a whole body SAR of 1W/kg for imaging landmarks within 30 cm of the implant.
- 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. This device has not been tested for heating or migration 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 INVERTA® Implants Product Catalogue
CAT-2070 - Zygomatic Implants Product Catalogue
CAT-2093 - Single Platform Implants Product Catalogue
CAT-2095 – External Hex INVERTA® 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.