SOUTHERNIMPLANTS®
Innovative Treatment Solutions

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Intended Use
Southern Implants® prosthetic retaining screws are intended to be used in the maxilla or mandible to connect an abutment or framework to an endosseous implant or abutment to restore chewing function for the patient.

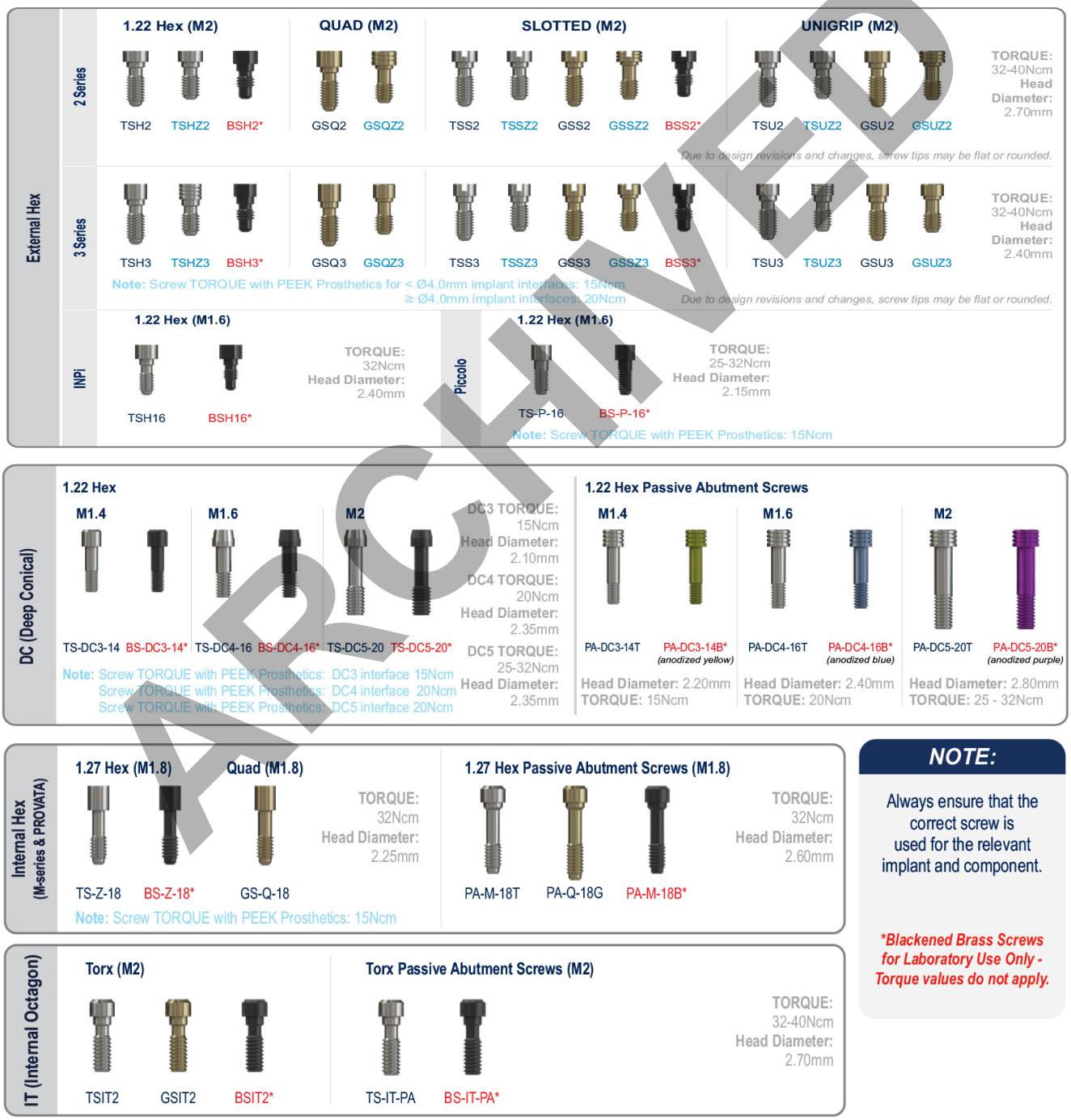
Intended User
Maxillo-facial Surgeons, General Dentists, Orthodontists, Periodontist, Prosthodontists, and other appropriately trained and experienced implant users.

Intended Environment
The devices are intended to be used in any standard autoclave as well as in the clinical environment such as an operating theatre or a dental consultation room.

Intended Patient Population
Patients that have lost one tooth or multiple teeth.

Description
These 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 and titanium screws. These components are supplied sterile and for single patient use. 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 5 implant connections.

Table A - Torque Table for Southern Screws



NOTE:

Always ensure that the correct screw is used for the relevant implant and component.

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

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

TRI-NEX

Unigrip (M1.8)

TS-L-18 | TS-L-18C (coated) | GS-L-18 | BS-L-18*

TORQUE: 32Ncm
Head Diameter: 2.50mm

Note: Screw TORQUE with PEEK Prosthetics: 15Ncm

Unigrip (M2)

TS-L-20 | TS-L-20C (coated) | GS-L-20 | BS-L-20*

TORQUE: 32-40Ncm
Head Diameter: 2.50mm

Note: Screw TORQUE with PEEK Prosthetics: 20Ncm

Unigrip Passive Abutment Screws (M1.8)

PA-L-18 | PA-L-18G | PA-L-18B*

TORQUE: 32Ncm
Head Diameter: 2.70mm

Unigrip Passive Abutment Screws (M2)

PA-L-20 | PA-L-20G | PA-L-20B*

TORQUE: 32-40Ncm
Head Diameter: 2.70mm

Compact Conical Abutment Level Screws

Series 1 Screws (M1.4)

1.22 Hex

TSH1 | GSH1 | BSH1*

Slotted

TSS1 | GSS1 | BSS1*

Unigrip

TSU1 | GSU1

TORQUE: 10-15Ncm
Head Diameter: 2.25mm

Note: Screw TORQUE with PEEK Prosthetics: 10 - 15Ncm

Angled Compact Conical Abutment Screws

External Hex

Series 9 & 9Z Screws (M2)

Slotted

GSS9

Unigrip

TSU9 | GSU9 | TSUZ9 | GSUZ9

TORQUE: 20Ncm
Head Diameter: 2.50mm

Internal Hex (M-series & PROVATA)

1.27 Hex

TS-Z-MC-18

TORQUE: 32Ncm
Head Diameter: 2.20mm

DC (Deep Conical)

1.22 Hex

TS-DC3-MC

TORQUE: 15Ncm
Head Diameter: 2.0mm

TS-DC4-MC

TORQUE: 20Ncm
Head Diameter: 2.0mm

TRI-NEX

Unigrip

TU-MCL-18C (coated) | GU-MCL-18

TORQUE: 20Ncm
Head Diameter: 2.25mm

TU-MCL-20C (coated) | GU-MCL-20

TORQUE: 20Ncm
Head Diameter: 2.45mm

Procera System

Unigrip (M2)

TSP2 | TSP2C (coated)

TORQUE: 32-40Ncm
Head Diameter: 2.50mm

Screw Connections

Hexed | Unigrip | Quad | Slotted | Torx

G.. = Gold Alloy
T.. = Gr. 5 Titanium Alloy
B.. = Brass

Table 2 - Southern Drivers

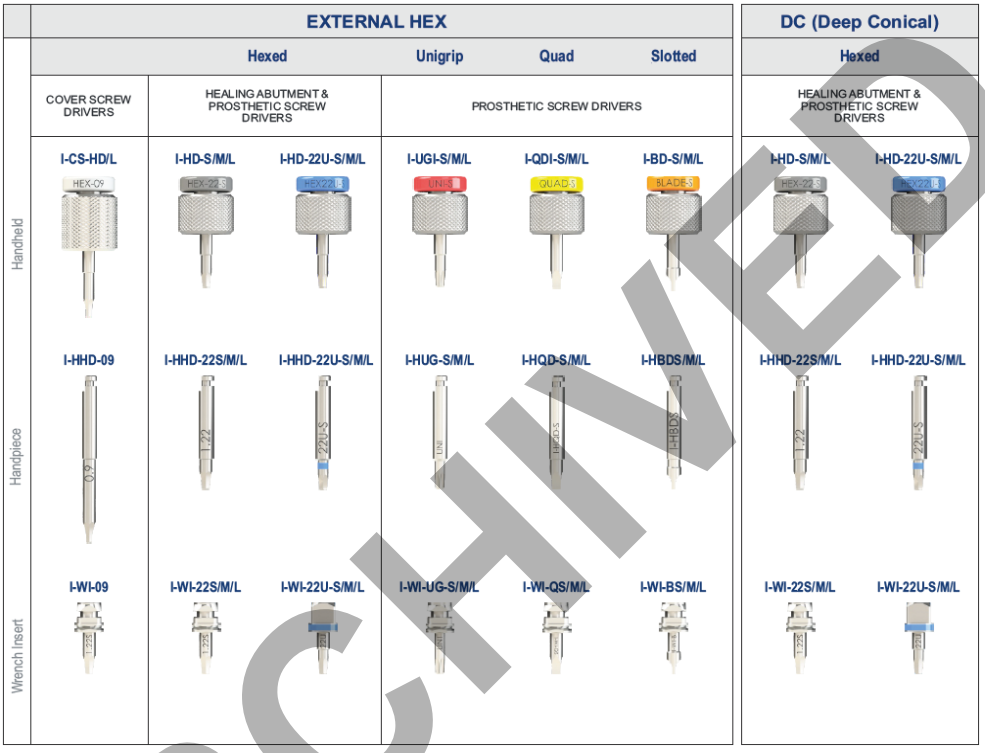
Southern Implants is introducing the new 1.22/1.27 Universal Hex drivers in hand-held, hand-piece and wrench insert versions. The advantage is that the same driver can be used on both 1.22 and 1.27 HEX driving interfaces – this does not include 0.9 HEX interfaces. The Universal Hex driver will allow 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 (i.e. usable on 1.27 Hex interfaces as well).

Product Codes:
- hand-held: I-HD-22U-S/M/L
- hand-piece: I-HHD-22U-S/M/L
- wrench insert: I-WI-22U-S/M/L

Colour coding:
- hand-held: blue idler.
- hand-piece: blue band on tool shaft.
- wrench insert: blue band on square feature of the wrench insert.

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.

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



Indications for Use

Southern Implants Prosthetic screws are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols:

- replacing single and multiple missing teeth in the mandible and maxilla.
- immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge.
- immediate loading in all indications, except in single tooth situations on implants shorter than 8mm or soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate.

Contraindications

- 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
- Sinus pathology

Warnings

THESE INSTRUCTIONS ARE NOT INTENDED AS A SUBSTITUTE FOR ADEQUATE TRAINING.

- For the safe and effective use of dental implants it is 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 and periodontal health.
- 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.
- 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.

During surgery

Care must be taken that parts are not swallowed or aspired during any of the procedures, a rubber-dam application is recommended when appropriate. Care must be taken to apply the correct tightening torque of abutments and abutment screws.

Post-surgery

Regular patient follow-up, and proper oral hygiene must be achieved to ensure favourable long-term results.

Procedure for use

1. Select the appropriate screw for the implant or abutment based on the product catalogue.
2. Using the appropriate driver (Table B), insert the retaining screw into the abutment or framework and connect the assembly to the implant or Compact Conical abutment.
3. Tighten the screw with an appropriate driver to the torque specified in Table A

Caution: Do not exceed the recommended insertion torques for retaining screws. Overtightening may result in screw fracture.

Storage, cleaning and sterilisation

The screws are single use for use on a single patient. If packaging is damaged do not use the product and contact your Southern representative/ or return to Southern Implants. The devises must be stored in a dry place at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics.

Storage, cleaning & sterilisation

The implants, cover screws and healing abutments are 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. Do not reuse implants, cover screws, temporary abutments and abutments.

Re-using these components may result in:

- 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 components

Clinical benefits

Patients can expect to have their missing teeth replaced and/ or crowns restored. Screwdrivers are used in dental procedures or in dental implant crowns & bridges.

Healing

The healing time required for osseointegration depends on the individual and treatment protocol.

Implant care and maintenance

Potential implant patients should establish an adequate oral hygiene. regime prior to Implant therapy. Proper post-operative, oral hygiene and implant maintenance instructions must be discussed with the patient, as this will determine the longevity and health of the Implants. The patient should maintain regular prophylaxis and evaluation appointments. It is the responsibility of the practitioner to decide when the implant can be restored. Good primary stability will govern if immediate loading can be done.

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%

Side effects

Potential Side Effects and Temporary symptoms: Pain, swelling, phonetic difficulties, 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.

MR Safey
These products have not been tested for MRI safety, however, an analysis and review of the literature has shown that the risks of scanning a Southern Implants implant system are not of concern under the following conditions:
- a static magnetic field of 1.5 Tesla and 3 Tesla.
- a magnetic field with a field gradient of 30T/M (3000G/cm).
- a whole body specific absorption rate (SAR) of 2W/kg, for 15 minutes of scanning.

Breakage
Implant and abutment fractures can occur when applied loads exceed the normal functional torque strength of the material. Potential overloading conditions may result from; deficiencies in implant numbers, lengths and/or diameters to adequately support a restoration, excessive cantilever length, incomplete abutment seating, abutment angles greater than 30 degrees, occlusal interferences causing excessive lateral forces, patient parafunction (e.g., bruxing, clenching), loss or changes in dentition or functionality, inadequate prosthesis fit, and physical trauma. Additional treatment may be necessary when any of the above conditions are present to reduce the possibility of hardware complications or failure.

Changes in performance
It is the responsibility of the clinician to instruct the patient on all appropriate contraindications, side effects, and precautions as well as the need to seek the services of a trained dental professional if there are any changes in the performance of the implant (e.g., looseness of the prosthesis, infection or exudate around the implant, pain, or any other unusual symptoms that the patient has not been told to expect).

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.

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.

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

Basic UDI

Product	Basic-UDI Number
Basic-UDI for Metal Abutments	600954403872

Related literature & 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 - INVERTA® Implants Product Catalogue
CAT-2070 - Zygomatic Implants Product Catalogue

Symbols and Warnings

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CE 2797 — Rx ONLY Prescription device* — STERILE R Sterilization using Irradiation — NON STERILE Non-sterile — Caution — Consult instruction for use — Use by date (mm-yy) — 2 Do not reuse — 2 STERILIZE Do not re-sterilize — LOT Batch code — Do not use if package is damaged — MD Medical Device

* 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.