SOUTHERNIMPLANTS®
Innovative Treatment Solutions

English	**INSTRUCTIONS FOR USE: Southern Implants® Screwdrivers: Handheld, Wrench insert and Handpiece "Latch"**
Español	**INSTRUCCIONES DE USO: Southern Implants® Screwdrivers: Handheld, Wrench insert and Handpiece "Latch"**
Italiano	**ISTRUZIONI PER L'USO: Southern Implants® Screwdrivers: Handheld, Wrench insert and Handpiece "Latch"**
Français	**MODE D'EMPLOI : Southern Implants® Screwdrivers: Handheld, Wrench insert and Handpiece "Latch"**
Deutsch	**GEBRAUCHSANWEISUNG: Southern Implants® Screwdrivers: Handheld, Wrench insert and Handpiece "Latch"**
Português	**INSTRUÇÕES DE UTILIZAÇÃO: Southern Implants® Screwdrivers: Handheld, Wrench insert and Handpiece "Latch"**

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Intended Use

Southern Implants® Screwdrivers are intended to be used to tighten and/or loosen, cover screws, healing abutments, Compact conical abutments, and screws used to connect dental implant components.

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 a clinical or laboratory environment such as an operating theater, dental laboratory or a dentist consultation room.

Intended patient population

This device is used in the dental restoration of partially or fully edentulous patients in the upper or lower jaw. Restorations may comprise of single teeth, partial or full bridges, and may be fixed or removable.

Description

Southern Implants screwdrivers are reusable instruments which are used in conjunction with Southern Implants clinical screws, abutment screws, prosthetic screws, and prosthetic components. These drivers are available in short, medium and long versions.

The handpiece "Latch" versions of the screwdrivers feature a latch and shaft section, with dimension compatible to ISO 1797. This is in order to connect the screwdriver to the handpiece of an implant motor unit.

The "Wrench" versions of the screwdrivers feature a square connection, to be used with the I-WI-SS wrench converter connected to the Southern Implants torque wrench.

The "Handheld" versions of the screwdrivers have an attached handle with a colour coded idler, to hold and turn the driver by hand.

Table A

	EXTERNAL HEX					DC (Deep Conical)	
	Hexed		Unigrip	Quad	Slotted	Hexed	
	COVER SCREW DRIVERS	HEALING ABUTMENT & PROSTHETIC SCREW DRIVERS	PROSTHETIC SCREW DRIVERS			HEALING ABUTMENT & PROSTHETIC SCREW DRIVERS	
Handheld	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	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	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)			TRI-NEX	IT (Internal Octagon)	Compact Conical Abutment
Hexed		Quad	Unigrip	Torx	
COVER SCREW, HEALING ABUTMENT & PROSTHETIC SCREW DRIVERS		GOLD PROSTHETIC SCREW DRIVERS	COVER SCREW, HEALING ABUTMENT & PROSTHETIC SCREW DRIVERS	COVER SCREW, HEALING ABUTMENT & PROSTHETIC SCREW DRIVERS	STRAIGHT COMPACT ABUTMENT DRIVERS
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-HHD-27S/M/L	I-HHD-22U-S/M/L	I-HQD-S/M/L	I-HUG-S/M/L	I-HSCS-S/M/L	I-HAD
					
I-WI-27S/M/L	I-WI-22U-S/M/L	I-WI-QS/M/L	I-WI-UG-S/M/L	I-WI-SCS-S/M/L	I-WI-A
					

Indications for use

Table A indicates the use of Southern Implants screw drivers. The drivers are indicated for use when a patient has undergone dental implant therapy and needs an abutment attached to the implant for healing or prosthetic purposes.

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, iridium, Stainless steel and Radel.
- 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.

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 informed consent rests with the practitioner. Improper technique can result in implant failure, damage to nerves/vessels and/or loss of supporting bone.
- The use of non-sterile items can lead to secondary infections of the tissue or transfer infectious diseases.

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 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.

Storage, cleaning & sterilisation
These devices are reusable and supplied non-sterile. 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.

Reusable devices:
Prior to reusing this device, it needs to be inspected, if there are signs of visible corrosion, deformed or twisted connections, dull cutting edges, expected wear and damage, this device shall be exposed of. After inspection, and reuse seems fit, the devices are cleaned, disinfected and sterilised.

General warning:
Do not reuse implants, cover screws, temporary abutments, abutments and single use devises. Reusing 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.

If re-use seems fit:
- Containment: As soon as practically possible, remove all visible residue after use (bone, blood or tissue), by immersing the instrument in cold water (Dried soil is difficult to remove).
- Pre-Cleaning: Rinse with lukewarm water for 3 minutes, and remove hardened debris with a soft nylon brush. Avoid mechanical damage during cleaning.
- Manual Cleaning or Automated Cleaning: Prepare an ultrasonic bath with suitable detergent, sonicate for 20 minutes (Alternative methods can be used if proven by the end user). Rinse with purified / sterile water. Load devices into a thermo-disinfector. Run the cleaning and disinfection cycle, followed by the drying cycle.

NOTE: Always follow the instructions for use of the manufacturers of cleaning agents and disinfectants.

- Drying: Dry the instruments with filtered compressed air or single use lint free wipes. Pack the instruments as quickly as possible after removal into the storage container. If additional drying is necessary, dry in a clean location. Moisture on these devices can cause corrosion and deterioration of the cutting edges.
- Inspection: Do a visual inspection of the items to check for any damage.
- Packaging: Use the correct packaging material as indicated for steam sterilisation to ensure sterility is maintained. Double packaging is recommended.

Sterilisation
Southern Implants recommends the following procedure to sterilise the instruments prior to use/re-use:

Methods to sterilise the surgical instruments:
1. Pre-vacuum Sterilisation method: Steam sterilise the instruments at 132°C (270°F) at 180-220kPa for 4 minutes. Dry for at least 20 minutes in the chamber. Only an approved wrap or pouch for steam sterilisation must be used.
2. Pre-vacuum 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.

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.

Handling procedures

Handheld screwdrivers
1. Before use loop dental floss through the hole in the idler attached to the handle of the handheld screwdriver, this is to prevent dropping the instrument in the patients mouth which could be swallowed or inhaled.
2. Engage the screwdriver to the component with light pressure.
3. Tighten or loosen the screw/component by hand.

Handpiece latch screwdrivers
1. Connect the handpiece latch screwdriver to the handpiece **Note:** If the latch is not inserted fully into the handpiece and the torque is applied to the tip or latch, resulting in possible twisting of the tip or damage to top of the latch. Consult the instructions for use of the handpiece to ensure proper engagement of the latch.
2. Engage the component to the handpiece driver with light pressure.
3. Set the motor unit to the correct torque value of the screw/ component being inserted, for torque values please see individual abutment IFU'S.

Do not apply more than 40-45Ncm to any latch type instrument, this could cause damage to the handpiece and latch of the instrument.

Wrench screwdrivers
1. Connect the wrench screwdriver to the manual torque wrench adaptor (I-WI-SS)
2. Connect the wrench driver connected to the I-WI-SS to the screw or component with light pressure.
3. Connect the manual torque wrench to the driver and/wrench adaptor assembly and tighten the screw/components to the recommended torque value, for torque values please see individual abutment IFU'S

Caution: Never exceed recommended maximum tightening torque in applicable instructions for use of the surgical or prosthetic component. Overtightening of the screw may lead to a screw fracture and/or damage of the component. Do not torque less than the recommended value, this may result in loosening of the screw or abutment.

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.

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.

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.

Materials
Handpiece "latch "drivers: Stainless Steel
Hand held drivers: Stainless Steel (Shaft) Idler: Radel
Wrench drivers: Stainless steel

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.

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.

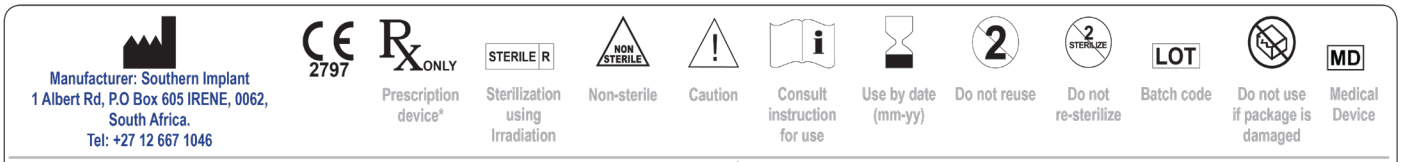
Notice regarding serious incidents
Any serious incident that has occurred in relation with the device must be reported to the manufacturer of the device and the competent authority in the member state in which the user and / or patient is established.
The contact information for the manufacturer of this device to report a serious incident is as follows: sicomplaints@southernimplants.com

Basic UDI

Product	Basic-UDI Number
Basic-UDI For Reuasble Instruments	600954403876

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



* 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.