SOUTHERNIMPLANTS®
Innovative Treatment Solutions

English	**INSTRUCTIONS FOR USE: Southern Implants® Screw Removers drills and guides**
Español	**INSTRUCCIONES DE USO: Southern Implants® Taladros y guías para quitar tornillos**
Italiano	**ISTRUZIONI PER L'USO: Southern Implants® Punte e guide per rimozione viti**
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Deutsch	**GEBRAUCHSANWEISUNG: Southern Implants® Bohrer und Führungen zum Entfernen von Schrauben**
Português	**INSTRUÇÕES DE UTILIZAÇÃO: Southern Implants® Brocas e guias para remoção de parafusos**

South Africa - Headquarters: 1 Albert Road, Irene, 0062, RSA
T: +27-12-667-1046 | **E:** info@southernimplants.com

EC REP
Southern Implants Europe AB: Holmgatan 30, S-791 71 Falun, Sweden
T: +46 23 13300 | **E:** ecrep@southernimplants.com

Subsidiaries

Australia
Southern Implants Australia
T: +61-(0)-8-9466-2627
E: info@southernimplants.com.au

Spain and Portugal
Southern Implants Iberica
T: +34 935 053 507
E: info@southernimplants.es

United Kingdom and Ireland
Southern Implants UK
T: +44-20-8899-6845 / 6 / 7
E: info@southernimplants.co.uk

USA and Canada
Southern Implants North America Inc.
T: +1-561-472-0990
E: customercare@southernimplants.com

Intended Use
Screw removers are intended to be used to remove broken screws from an implanted dental implant. The screw removers are medical devices. They are intended for single use on a single 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 a clinical environment such as an operating theater or a dentist consultation room.

Intended patient population
Patients that have lost one tooth or multiple teeth and have had dental implants inserted.

Description
Southern Implants screw removers drills and guides are described in table A. The screw remover drills attach to a handpiece of an implant motor unit, and has a latch compatible to ISO 1797. This is in order to connect the drill to the handpiece of an implant motor unit. Screw remover has laser marking on the shaft of the drill, to indicate the product code. The I-SR-6 has a 1.15mm cutting tip, the I-SR-3 screw remover has cutting threads that cut with a counterclockwise rotation when rotated by a dental handpiece. Drill guides are anodized to the prosthetic diameter of the implant as described in table A. These devices are supplied non-sterile, and for single use only.

Indications for use
The screw removers are indicated for use in patients that have undergone dental implant therapy where a screw has broken off in the implant and that screw needs to be removed so that the implant can be restored with a new screw.

TABLE A

DRILL GUIDES

EXTERNAL HEX	TRI-NEX	DC (DEEP CONICAL)	INTERNAL HEX (PROVATA® & M-SERIES	IT (INTERNAL OCTA-GON)
I-SRG-MSC-IP 3mm Diameter Piccolo Implant  **I-SRG-IBN** 3.25mm Diameter IBN/T Implant  **I-SRG-EXT-HEX** Other Ex Hex Implants 	**I-SRG-L-35** 3mm Diameter Piccolo Implant  **I-SRG-L-43** 3mm Diameter Piccolo Implant  **I-SRG-L-50** 3mm Diameter Piccolo Implant  **I-SRG-L-60** 3mm Diameter Piccolo Implant	**I-SRG-DC3** 3mm Diameter Piccolo Implant  **I-SRG-DC4** 3mm Diameter Piccolo Implant  **I-SRG-DC5** 3mm Diameter Piccolo Implant 	**I-SRG-M** 3mm Diameter Piccolo Implant  **DRILLS**  **I-SR-6**	**I-SRG-IT** 3mm Diameter Piccolo Implant   **I-SR-3**

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.

English **INSTRUCTIONS FOR USE: Southern Implants® Screw Removers drills and guides**

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.

Surgical procedures for screw removal

Step 1

The use of a fine probe to gently rotate the broken screw in an anti-clockwise direction, may often turn the screw out, to the point that it may be gripped with a haemostat and rotated out fully. The screw is usually quite loose once it has fractured, and should be freely able to rotate.

Step 2

Should step 1 not be successful and the screw is not loose, the use of an ultrasonic scaler in the same manner as the probe, should be applied. Often, the ultrasound assists in the rotation/freeing up of the screw. Once the screw has been exposed to ultrasound, Step 1 should be applied a second time,

Step 3

If the ultrasound is not successful on its own. The correct drill guide must be selected for the corresponding implant. Place the guide on top of the implant interface, It must be ensured that the drill guide is correctly seated on the implant interface. Each drill guide has a square connection on the opposing end, allowing them to be stabilized using a ratchet or torque wrench. The screw removal drills rotate in a counter-clockwise direction. The first drill, (I-SR-6), cuts a pilot hole in the center of the screw to be removed. It is possible that the drilling process of the I-SR-6 may thread the screw out of the implant, if the drill grips the screw while cutting the pilot hole.

NOTE:

- the screw removal instrumentation may only be used with a high torque – low speed motor unit, in reverse set at 600 – 800 rpm for the I-SR-6 with copious irrigation, and 10 - 20 rpm for the I-SR-3. Do not overheat the implant via friction this can lead to failure of the implant.
- gently insert the drill into the latch-grip handpiece, ensuring that it is fully engaged. If the latch is not properly engaged in the handpiece, the torque applied when activating the motor unit may result in the possible distortion of the latch or damage to the handpiece, due to the incorrect distribution of forces within the latch-grip mechanism.
- consult the instructions for use of the relevant handpiece manufacturer, to ensure proper engagement of the latch.
- do not apply more than 40-45Ncm to any latch type instrument. This could cause damage to the handpiece gearing mechanism, and/or latch of the instrument.

Step 4

If step is not successful the, I-SR-3 will be used. Once the pilot hole has been cut by the I-SR-6, the I-SR-3 is designed to wedge into and engage the internal walls of the pilot hole, and rotate the fractured screw out in a counter-clockwise direction. Should this not be successful, a small rose head bur may also be tried to rotate the screw out by hand.

After successes screw removal , it is important to ensure that the internal thread of the implant has not been damaged. This can be done using a healing abutment or impression coping pin. Should there be significant resistance when checking the internal thread for damage, it may be necessary to clean the internal thread of the implant by carefully using a thread tap.

Storage, cleaning & sterilisation

These devices are for single use 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.

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.

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.

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.

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.

Material

Drill guides:	Titanium grade 5
I-SR-3:	Stainless steel
I-SR-6:	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
TD-DHP Basic-UDI for Drills and Hand Piece Devices	600954403875

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

Manufacturer: Southern Implants
1 Albert Rd, P.O Box 605 IRENE, 0062,
South Africa.
Tel: +27 12 667 1046

Prescription device*

Sterilization using Irradiation

Non-sterile

Caution

Consult instruction for use

Use by date (mm-yy)

Do not reuse

Do not re-sterilize

Batch code

Do not use if package is damaged

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.