SOUTHERNIMPLANTS®
Innovative Treatment Solutions

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

EC REP

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
Southern Implants® pilot drills are intended to be used to prepare the osteotomy for Implant placement.

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

Intended environment
The pilot drills are intended to be used in a clinical environment such as an operating theater 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 single teeth, partial or full bridges, and may be fixed or removable.

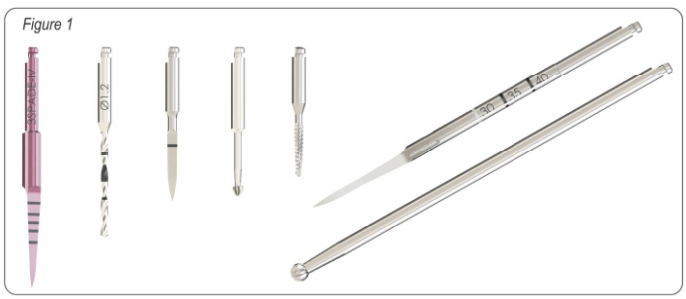
Description
Southern Implants Pilot Drills are made of surgical grade stainless steel or Titanium (Grade 4). The drills have either a round tip or a spade tip design and some are anodised, as described in Table 1 and Figure 1 respectively. The drills have a latch dimension compatible to ISO 1797. This is in order to connect the drill to the handpiece of an implant motor unit. Drill sizes are identified by laser markings on the shaft of the drill. Some pilot drills have laser markings to indicate the drill depth.

Pilot drills indicated in Table 1 are provided sterile:
- Pilot drills indicated, with 1 Number of uses is for single use only.
- Pilot drills indicated with 10 Number of uses, can be used up to 10 times or when the cutting efficiency deteriorates.

Table 1

Drill code	Material	Coating (if any)	Descripton of product	Number of uses
External Hex, Tri-Nex, Internal Hex (M-series & Provata), DC (Deep Conical), Inverta and IT (Internal Octagon)				
D-RS-MS	Surgical Stainless Steel	1000- 1500 Rpm	Drill Round Burr	1
D-3SPADE-1.8M	Surgical Stainless Steel	1000- 1500 Rpm	Drill Spade Ø1.8 mm	1
D-3SPADE-IV	TiGr4 Anadised	1000- 1500 Rpm	Drill Spade Ø1.2 mm	1
D-3SPADE-IVSS	TiGr4 Anadised	1000- 1500 Rpm	Drill Spade Ø1.2 mm	1
D-12T-M15	Surgical Stainless Steel	1000- 1500 Rpm	Drill Twist Ø1.2 mm	1
D-16-T	Surgical Stainless Steel	1000- 1500 Rpm	Drill Twist Ø1.6 mm	1
Zygomatic, Oncology, Zygan & Zygex implants				
D-ZYG-RB	Surgical Stainless Steel	1000- 1500 Rpm	Drill Round Burr	1
D-3SPADE-ZYG	TiGr5	1000- 1500 Rpm	Drill Spade Ø2.0 mm	1

Figure 1



Indications for use of our pilot drills
Southern Implants pilot drills are indicated as the first step in Southern Implants drill protocol. The pilot drills initiate the osteotomy by perforating the cortical plate at the desired location to provide a guide for the subsequent drills.

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 or stainless steel.
- 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 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.
- The use of non-sterile items can lead to secondary infections of the tissue or transfer infectious diseases.
- Blunt drills may cause damage to the bone which could compromise osseointegration.

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. 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 or equipment.

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 supplied sterile (sterilised by gamma irradiation).

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.

Single use devices:
Do not reuse devices indicated for single use. (Use the device prior to the expiration date).
Do not reuse implants, single use drills, cover screws, temporary abutments and abutments. 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 when packed in a tray.

Methods to sterilise these devises:

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 procedure

A proper clinical and radiological evaluation must be done to determine the bone dimensions and bone quality.

Surgical procedure

Southern Implants provides the user with different drill options, for placement of implants. Refer to each individual product catalogue for different drill protocols for specific implants and bone quality.

1. The bone is exposed by either doing open or flapless surgery.
2. The pilot drill is used to initiate the osteotomy by perforating the cortical plate at the desired location.

Note: Connect the drill latch to the handpiece. If the latch is not inserted fully into the handpiece the torque is applied to the latch, resulting in possible twisting of the latch or damage to the handpiece. Consult the instructions for use of the handpiece to ensure proper engagement of the latch.

3. All drilling should be performed at a speed of 1000-1500rpm with copious irrigation. Do not apply lateral forces to the drill.
4. Use an up-and-down motion with the hand piece, without stopping the motor. This will allow the irrigation to flush away bone debris on the drill.

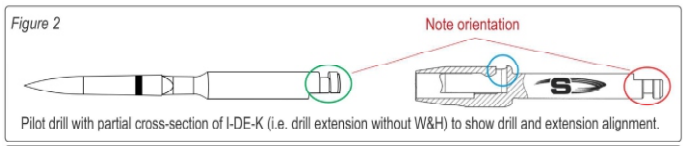
Note: Extra caution should be taken when using narrow diameter drills, (such as the D-12T-M15).

- Avoid lateral pressure (bending) on the drills during drilling procedures.
- Lateral pressure to the drill can cause drill fracture.
- Verify the drill is securely locked into the hand piece before drilling procedure starts.

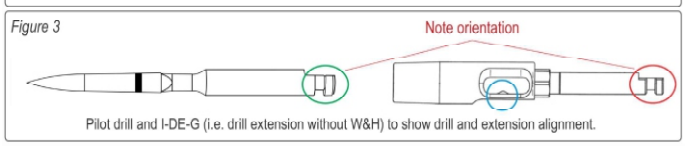
Drill extensions

When a drill extension is used (I-DE-K / I-DE-G), care must be taken to ensure that the latch is fully engaged to prevent distortion. See Figure 2 and Figure 3 below.

- Drill extensions must NOT be used with ø6mm and larger drills, use longer shaft drills instead.
- Drill extensions must NOT be used with Bone taps.



Pilot drill with partial cross-section of I-DE-K (i.e. drill extension without W&H) to show drill and extension alignment.



Pilot drill and I-DE-G (i.e. drill extension without W&H) to show drill and extension alignment.

The orientations indicated in Figure 2 and Figure 3 ensure that the catch feature of the drill extension (circled in blue) slots into the latch groove of the drill (circled in green). This prevents the drill from sliding out of the drill extension.

Note:

- Do not apply more than 40-45Ncm to any latch type drill/ instrument, this could cause damage to the handpiece and latch of the instrument.
- Blunt drills cause excessive torque and result in damage to the handpiece or drill latch.

Materials

Drills: Surgical Stainless Steel, or Titanium (Grade 4).

Clinical benefits

Through this procedure patients can expect to have their missing teeth replaced and/ or crowns restored.

Healing

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

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 Drills and Hand-piece Devices	600954403875

Related literature & catalogues

CAT-2004- Tri-Nex Implants Product Catalogue
CAT-2005- IT Implants Product 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.