

Intended Use:

Southern Implants Initial drills are intended to be used to prepare the osteotomy for Implant placement. The Initial drills are made from surgical grade Stainless steel, the Initial drills either has a round tip or a spade design (Refer to figure 1.1). And is for single use only.

Table 1.

A	D	E	F	G
External Hex, TRI-NEX, Internal Hex (M-series & Provata), DC (Deep Conical) and IT (Internal Octagon)				
Product code	Material	Speed	Description of product	Number of uses
D-RB-MS	Surgical Stainless steel	1000-1500Rpm	Drill Round Burr	1
D-3SPADE-1.5L	Surgical Stainless steel	1000-1500Rpm	Drill Spade ø1.5 x 19mm in length	1
D-3SPADE-1.8M	Surgical Stainless steel	1000-1500Rpm	Drill Spade ø1.8 x 16mm in length	1
D-12T-M15	Surgical Stainless steel	1000-1500Rpm	Drill Twist ø1.2mm	1
D-16-T	Surgical Stainless steel	1000-1500Rpm	Drill pilot side cutting ø1.6mm	1
Zygomatic, Oncology, Zygan & Zygex implants				
D-ZYG-RB	Surgical Stainless steel	1000-1500Rpm	Drill Round Burr	1

Indications for use of Our implant systems:

Southern Implants' Dental Implants are intended to be implanted in the upper or lower jaw arches to provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses or full-arch prostheses to restore chewing function.

Indications for use of OUR pilot drills:

Southern Implants Pilot Drills are indicated as the first step in Southern Implants Drill protocol, the Pilot Drill initiate the osteotomy by perforating the cortical plate at the desired location to allow for the subsequent drills to have a stable start. Indicated for Southern implant systems as in Table 1.

Contraindications

Do not use in patients:

- who are medically unfit for dental implant procedures (e.g. uncontrolled diabetes and untreated infection in nearby bone).
- who are allergic to or have hypersensitivity to pure Titanium, Titanium Alloy (Ti-6AL-4V), Aluminium Titanium Nitride (AlTiN) or stainless steel.
- where adequate numbers of implants cannot be placed to achieve full functional support for a prosthesis.

Warnings:

- 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.
- 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 undergo 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 (e.g. patients that have had oro-facial radiotherapy, poor oral hygiene, patients on steroid therapy and smokers).
- 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, periodontal status, and adequacy of bone.
- 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.

During procedure:

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

Post-procedure:

- Regular patient follow-up, and proper oral hygiene must be achieved are essential for favourable long-term results.

Clinical procedures:**Case Planning:**

A proper clinical and radiological evaluation must be done to determine the bone dimensions and bone quality. Ensure that all instruments and drills are in a good condition. Blunt drills may cause damage to the bone which will compromise osseointegration.

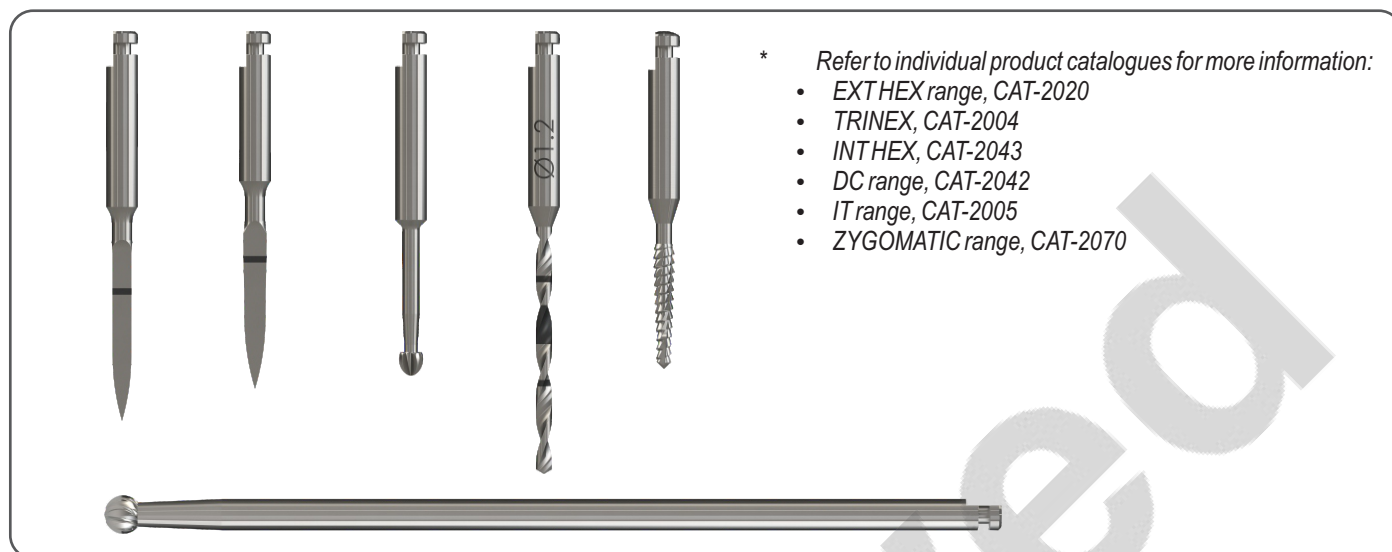
Surgical:

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

The drill sizes are identified by different laser markings on the shaft of the drill. The drills have different laser markings on the cutting surface of the drill which corresponds to the length of implant being placed.

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.
3. All drilling should be performed at a speed of 1000-1500Rpm with copious irrigation.
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.

Pilot drills do not have laser markings on the shaft of the drill.



NOTE: When used with a drill extension, care must be taken to ensure that the latch is fully engaged to prevent distortion.

Magnetic Resonance (MR) safety information:

This device has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artefact in the MR environment. The safety of this device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Storage, Cleaning & Sterilization:

Southern Implants drills are supplied sterile. Please refer to individual product label for more information.

The outer portion of the packaging consists either of a rigid, clear plastic-formed "blister" with a "peel-back" lid. Labelling information is located on the surface of the peel-back lid. Sterility (where applicable) is assured unless the container or seal is damaged or opened. Or in a peel pouch, with the Labeling information located in the bottom half of the Peel pouch. Items supplied non-sterile must be cleaned and sterilized before use.

Warning: The use of non-sterile items can lead to secondary infections of the tissues or transfer of infectious diseases.

If the drills has been opened and placed in the surgical tray prior to surgery and sterilization seems fit:

- Instrument trays should be autoclaved at 121°C or 250°F for 30 minutes or at 134-137°C for 3-7 minutes with sufficient drying cycle to avoid instrument corrosion.
- **Pre-vacuum sterilization:** Steam sterilize the components at 132°C (270°F), at 180 - 220 kPa for 4 minutes, or at 135°C (275°F), at 180 - 220 kPa for 3 minutes. Dry for at least 20 minutes in the chamber.
- **Note:** Only an FDA or appropriate regulatory authority approved wrap or pouch for steam sterilization must be used. It is the responsibility of the user to establish whether or not their sterilizer is approved by an appropriate regulatory authority to meet recommended parameters.
- **Storage:** Maintain packaging integrity to ensure sterility in storage. Packaging should be dry before storage to avoid corrosion and degradation of cutting edges. Device should be stored at room temperature and not exposed to direct sunlight.

Disposal

Disposal of the device and its packaging shall follow local regulations and environmental requirements, taking different contamination levels into account.

Symbols & Warnings

 Manufacturer: Southern Implants 1 Albert Rd, P.O. Box 605 IRENE, 0062, South Africa. Tel: +27 12 667 1046 Fax: +27 12 667 1029	 0086 	 Rx ONLY Prescription device *	 STERILE R Sterilization using Irradiation	 NON-STERILE Non-sterile	 Caution	 Consult instruction for use	 Use by date (mm-yy)	 Do not reuse	 Do not Re-sterilize	 LOT Batch code	 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 licensed physician or dentist.						Canada license exemption: Please note that not all products may have been licensed in accordance with Canadian law.					
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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.