

**Intended Use:**

Southern Implants cylindrical twist drills and cylindrical bone taps, are intended to be used to prepare the osteotomy for implant placement. The cylindrical twist drills are designed with laser markings on the body corresponding to implant length to assist with drilling depths.

Refer to Table 1 to determine if re-use is possible.

**Description:**

These drills are made of stainless steel or Titanium Alloy (Grade 5) and some are AlTiN coated (refer to Table 1 for specific details).

Table 1. Twist drills

Drill code	Material	Coating (if any)	Description of product	Number of uses
<b>External Hex, Internal Hex (M-series &amp; Provata), TRI-NEX</b>				
D-20T-MXX	Stainless Steel		Twist Drill ø2	1
D-25T-MXX	Stainless Steel		Twist Drill ø2.5	1
D-29T-MXX	Stainless Steel		Twist Drill ø2.85	1
D-30T-MXX	Stainless Steel		Twist Drill ø3	1
D-33T-MXX	Stainless Steel		Twist Drill ø3.25	1
D-35T-MXX	Stainless Steel		Twist Drill ø3.5	1
D-40T-MXX	Stainless Steel		Twist Drill ø4	1
D-43T-MXX	Stainless Steel		Twist Drill ø4.3	1
D-46T-MXX	Stainless Steel		Twist Drill ø4.6	1
D-50T-MXX	Stainless Steel		Twist Drill ø5	1
D-53T-MXX	Stainless Steel		Twist Drill ø5.3	1
D-56T-MXX	Stainless Steel		Twist Drill ø5.6	1

Drill code	Material	Coating (if any)	Description of product	Number of uses
<b>IT (Internal Octagon)</b>				
D-220C	Stainless Steel		Twist Drill $\varnothing 2.2$	1
D-275C	Stainless Steel		Twist Drill $\varnothing 2.75$	1
D350C	Stainless Steel		Twist Drill $\varnothing 3.5$	1
D-430C	Stainless Steel		Twist Drill $\varnothing 4.3$	1
D-22C-L	Titanium		Twist Drill $\varnothing 2.2$ , Longer shaft drill	10
D-275C-L	Titanium		Twist Drill $\varnothing 2.75$ , Longer shaft drill	10
D-350C-L	Titanium		Twist Drill $\varnothing 3.5$ , Longer shaft drill	10
D-430C-L	Titanium		Twist Drill $\varnothing 4.3$ , Longer shaft drill	10
<b>DC (Deep Conical)</b>				
D-DC20	Stainless Steel	ALTiN	Twist Drill DC $\varnothing 2.2$	20
D-DC25	Stainless Steel	ALTiN	Twist Drill DC $\varnothing 2.5$	20
D-DC27	Stainless Steel	ALTiN	Twist Drill DC $\varnothing 2.7$	20
D-DC29	Stainless Steel	ALTiN	Twist Drill DC $\varnothing 2.85$	20
D-DC32	Stainless Steel	ALTiN	Twist Drill DC $\varnothing 3.2$	20
D-DC34	Stainless Steel	ALTiN	Twist Drill DC $\varnothing 3.35$	20
D-DC37	Stainless Steel	ALTiN	Twist Drill DC $\varnothing 3.7$	20
D-DC39	Stainless Steel	ALTiN	Twist Drill DC $\varnothing 3.85$	20
D-DC42	Stainless Steel	ALTiN	Twist Drill DC $\varnothing 4.2$	20
D-DC47	Stainless Steel	ALTiN	Twist Drill DC $\varnothing 4.7$	20
D-DC49	Stainless Steel	ALTiN	Twist Drill DC $\varnothing 4.8$	20
<b>Zygomatic, Oncology, Zygan &amp; ZygeX implants</b>				
D-ZYG-29	Titanium	Anodized yellow	Twist Drill Zygomatic $\varnothing 2.9$	1
D-ZYG-29S	Titanium	Anodized yellow	Twist Drill Zygomatic $\varnothing 2.9$ (Short)	1
D-ZYG-35	Titanium	Anodized yellow	Twist Drill Zygomatic $\varnothing 3.5$	1
D-ZYG-35S	Titanium	Anodized yellow	Twist Drill Zygomatic $\varnothing 3.5$ (Short)	1
<b>Guided Surgery</b>				
D-20T-GS-20	Titanium		Twist Drill Guided Surgery $\varnothing 1.95$	10
D-20T-GS-23	Titanium		Twist Drill Guided Surgery $\varnothing 1.95$	10
D-20T-GS-28	Titanium		Twist Drill Guided Surgery $\varnothing 1.95$	10
D-28T-GS-20	Titanium		Twist Drill Guided Surgery $\varnothing 2.75$	10
D-28T-GS-23	Titanium		Twist Drill Guided Surgery $\varnothing 2.75$	10
D-28T-GS-28	Titanium		Twist Drill Guided Surgery $\varnothing 2.75$	10
<b>FIRST</b>				
D-20T-32RT	Titanium		Twist Drill FIRST technique $\varnothing 2.0$	1
D-29T-32RT	Titanium		Twist Drill FIRST technique $\varnothing 2.85$	1
D-33T-32RT	Titanium		Twist Drill FIRST technique $\varnothing 3.25$	1
D-35T-32RT	Titanium		Twist Drill FIRST technique $\varnothing 3.5$	1
D-40T-32RT	Titanium		Twist Drill FIRST technique $\varnothing 4.0$	1
<b>EXTRA Oral</b>				
D-20E-03F	Titanium		Twist Drill IE implant $\varnothing 3.0 - 3\text{mm}$	1
D-20E-04F	Titanium		Twist Drill IE implant $\varnothing 3.0 - 4\text{mm}$	1
D-20E-06F	Titanium		Twist Drill IE implant $\varnothing 3.0 - 6\text{mm}$	1
D-30E-03F	Titanium		Twist Drill IE implant $\varnothing 4.0 - 3\text{mm}$	1
D-30E-04F	Titanium		Twist Drill IE implant $\varnothing 4.0 - 4\text{mm}$	1
D-30E-06F	Titanium		Twist Drill IE implant $\varnothing 4.0 - 6\text{mm}$	1

Table 1. Bone taps

Drill code	Material	Coating (if any)	Description of product	Number of uses
<b>External Hex</b>				
D-TAP-IBN	Titanium		Tap for Hard Bone IBN	10
D-TAP-IBS	Titanium		TAP for Hard Bone IB	10
D-TAP-I4B	Titanium		TAP for Hard Bone I4B 4mm	10
D-TAP-BA	Titanium		TAP for Hard Bone BA	10
D-TAP-BBBS	Titanium		TAP for Hard Bone BBB	10
<b>TRI-NEX</b>				
D-TAP-LS-35	Titanium		Tap for hard bone $\varnothing$ 3.5	10
D-TAP-LS-43	Titanium		Tap for hard bone $\varnothing$ 4.3	10
D-TAP-LS-50	Titanium		Tap for hard bone $\varnothing$ 5.0	10
<b>DC (Deep Conical)</b>				
D-TAP-DCC30	Titanium		Tap for hard bone $\varnothing$ 3.0	10
D-TAP-DCC35	Titanium		Tap for hard bone $\varnothing$ 3.5	10
D-TAP-DCC40	Titanium		Tap for hard bone $\varnothing$ 4.0	10
D-TAP-DCC50	Titanium		Tap for hard bone $\varnothing$ 5.0	10
<b>IT (Internal Octagon)</b>				
D-TAP-ITC3	Titanium		Tap for hard bone $\varnothing$ 3.1	10
D-TAP-ITC4	Titanium		Tap for hard bone $\varnothing$ 4.1	10
D-TAP-ITC5	Titanium		Tap for hard bone $\varnothing$ 4.9	10

**Note:**

Before preparing for sterilization, all medical devices should be inspected and checked for:

- signs of corrosion
- any damage that could affect sharpness of cutting edges.

**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 the chewing function.

**Indications for use of Our twist drills and cylindrical bone taps:**

Southern Implants cylindrical twist drills are indicated for a step-wise drilling approach when preparing an osteotomy in soft, normal and dense bone by following the drill protocols, as indicated in the product catalogues, for parallel walled implants.

Southern Implants' bone taps are indicated to pre-tap the bone when preparing an osteotomy in dense bone, by following the drill protocols as indicated in the product catalogues, to aid implant placement.

**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.

**Post-procedure**

- Regular patient follow-up, and proper oral hygiene 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.

**Surgical procedure:** Southern Implants provides the user with different drill options, for placement of cylindrical implants, refer to each individual catalogue for drill protocols for different bone quality. Ensure that all instruments and drills are in a good condition. Blunt drills may cause damage to the bone which could compromise osseointegration.

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

Figure 1



\* Refer to individual product catalogues for more information:

- EXT HEX range, CAT-2020
- TRINEX, CAT-2004
- INT HEX (M-series), CAT-2043
- DC range, CAT-2042
- IT range, CAT-2005

1. Drill in the planned direction to the full depth of implant length being placed as indicated on the markings on the drill. Cylindrical drills extend up to 1mm longer than the implant, when seated. Allow for this additional length when drilling near vital anatomical structures.
2. Drill at sufficient speed (between 1000-1500rpm for Cylindrical Drills), with constant irrigation with sterile saline.
3. 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.
4. Insert the Direction Indicator (I-DI) after using the 2mm Twist drill, to verify the alignment with adjacent implants or teeth. A radiograph can be taken at this stage to verify depth and direction. If the drilling direction is incorrect, start a new direction with the initial drill.
5. Gradually enlarge the osteotomy in a stepwise approach to the desired diameter and depth, the depth can be determined by a depth gauge:
  - I-DG-24 for External Hex, Internal Hex, IT and TRI-Nex Implants,
  - I-DG-DC for DC implants.
6. It is recommended to undersize the osteotomy in soft bone, and use to a bone tap in dense bone.

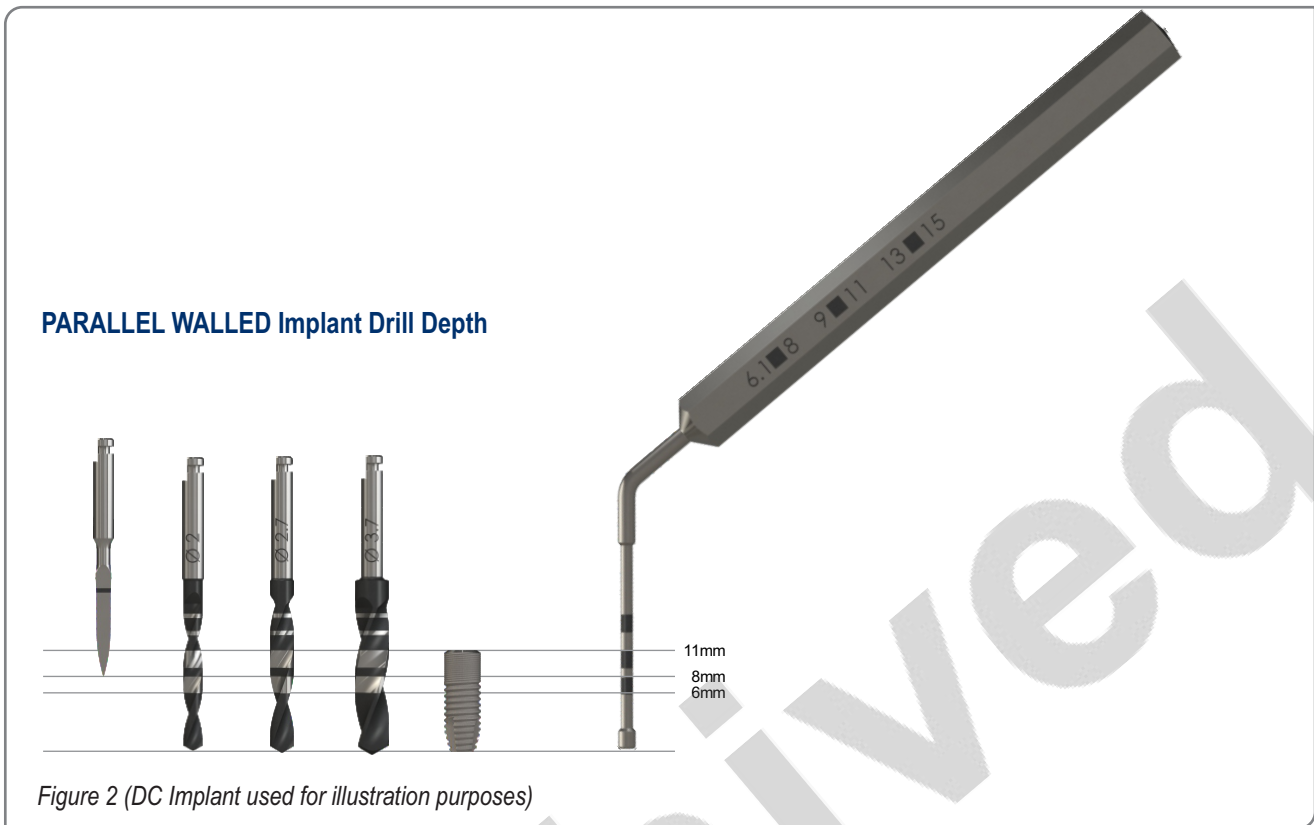
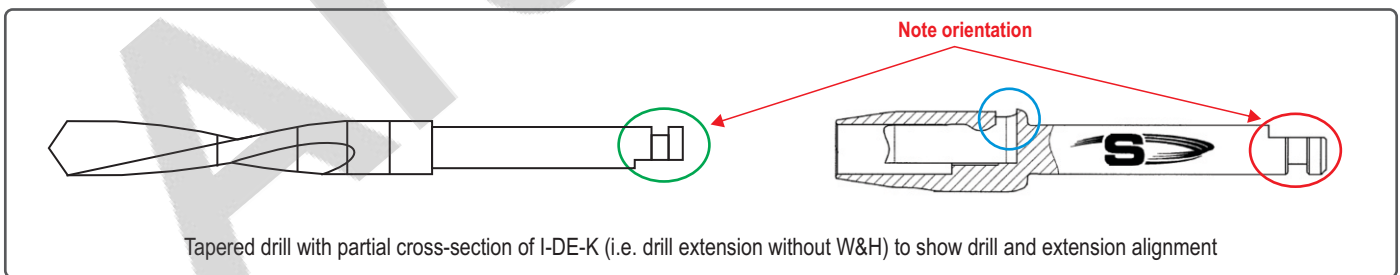


Figure 2 (DC Implant used for illustration purposes)

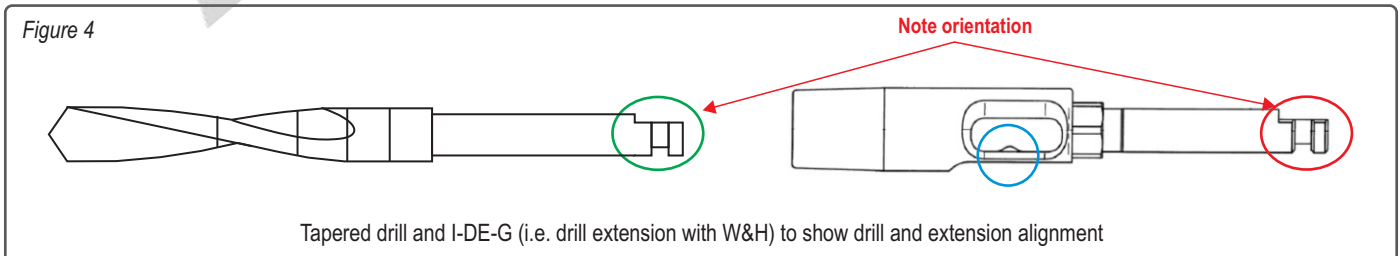
8. During surgery the clinician will be able to assess the bone quality and should use dense bone protocols when necessary, to prepare the site. This is to avoid the implant getting stuck before it is properly seated in the osteotomy.
9. Preparing the site further should involve: ensure the drill goes to full depth and/or use of the optional bone tap to pre-tap the site. Tap at low speed (25rpm) and after tapping to full depth, switch the hand-piece to reverse mode to remove the tap.

Note: 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 3 & Figure 4 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.



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



Tapered drill and I-DE-G (i.e. drill extension with W&H) to show drill and extension alignment

- **Zygomatic twist drills:**
  - Avoid lateral pressure 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.



## Materials

Drills: Stainless Steel, or Titanium Alloy (Ti-6AL-4V)  
 Drill Coating: None, or Titanium Nitride (TiN), or Aluminium Titanium Nitride (AlTiN)

## 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 tapered drills and bone taps are supplied sterile. The product must be stored in a dry place at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics. Do not use if original package is damaged. Sterility is assured unless the original packaging is damaged or opened.









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. If additional drying is necessary, dry in a clean location.
- **Note:** Moisture on drills can cause corrosion and deterioration of the cutting edges.
- **Inspection:** Do a visual inspection of the items to check for any damage/s.
- **Packaging:** Use the correct packaging material as indicated for steam sterilization to ensure sterility is maintained. Double packaging is recommended.
- **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	 CE 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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For Technical Assistance or additional product literature, please contact Southern Implants.

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## 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.