



SOUTHERNIMPLANTS®

Innovative Treatment Solutions

English	INSTRUCTIONS FOR USE: Southern Implants® Cylindrical Step Twist Drills and Taps
Español	INSTRUCCIONES DE USO: Southern Implants® Cylindrical Step Twist Drills and Taps
Italiano	ISTRUZIONI PER L'USO: Southern Implants® Cylindrical Step Twist Drills and Taps
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Archived



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

United Kingdom
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: customer care@southernimplants.com

Intended use

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

Description

Southern Implants cylindrical twist drills and cylindrical bone taps, are as described in Table 1 and Table 2, respectively. These drills are made of stainless steel or Titanium Alloy (Grade 5) and some are ALTiN coated.

Table 1. Twist Drills

Drill code	Material	Coating (if any)	Description of product	Number of uses
External Hex, Internal Hex (M-series & Provata), TRI-NEX				
D-20T-MXX	Stainless Steel	-	Twist Drill Ø2.0	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 Ø3.0	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 Ø4.0	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 Ø5.0	1
D-53T-MXX	Stainless Steel	-	Twist Drill Ø5.3	1
D-56T-MXX	Stainless Steel	-	Twist Drill Ø5.6	1
IT (Internal Octagon)				
D-220C	Stainless Steel	-	Twist Drill Ø2.2	1
D-275C	Stainless Steel	-	Twist Drill Ø2.75	1
D-350C	Stainless Steel	-	Twist Drill Ø3.5	1
D-430C	Stainless Steel	-	Twist Drill Ø4.3	1
D-220C-L	Titanium	-	Twist Drill Ø2.2 Longer shaft drill	1
D-275C-L	Titanium	-	Twist Drill Ø2.75 Longer shaft drill	1
D-350C-L	Titanium	-	Twist Drill Ø3.5 Longer shaft drill	1
D-430C-L	Titanium	-	Twist Drill Ø4.3 Longer shaft drill	1
DC (Deep Conical)				
D-DC20	Stainless Steel	ALTiN	Twist Drill DC Ø2.2	1
D-DC25	Stainless Steel	ALTiN	Twist Drill DC Ø2.5	1
D-DC27	Stainless Steel	ALTiN	Twist Drill DC Ø2.7	1
D-DC29	Stainless Steel	ALTiN	Twist Drill DC Ø2.85	1
D-DC32	Stainless Steel	ALTiN	Twist Drill DC Ø3.2	1
D-DC34	Stainless Steel	ALTiN	Twist Drill DC Ø3.35	1
D-DC37	Stainless Steel	ALTiN	Twist Drill DC Ø3.7	1
D-DC39	Stainless Steel	ALTiN	Twist Drill DC Ø3.85	1
D-DC42	Stainless Steel	ALTiN	Twist Drill DC Ø4.2	1
D-DC47	Stainless Steel	ALTiN	Twist Drill DC Ø4.7	1
D-DC49	Stainless Steel	ALTiN	Twist Drill DC Ø4.8	1
Zygomatic, Oncology, Zygan & Zygex implants				
D-ZYG-27	Titanium	Anodised yellow	Twist Drill Zygomatic Ø2.7	1
D-ZYG-27S	Titanium	Anodised yellow	Twist Drill Zygomatic Ø2.7 (Short)	1
D-ZYG-27ST-GSM	Titanium	Anodised yellow	Twist Drill Zygomatic Ø2.7 (Medium)	1
D-ZYG-27ST-GSL	Titanium	Anodised yellow	Twist Drill Zygomatic Ø2.7 (Long)	1
D-ZYG-29	Titanium	Anodised yellow	Twist Drill Zygomatic Ø2.9	1
D-ZYG-29S	Titanium	Anodised yellow	Twist Drill Zygomatic Ø2.9 (Short)	1

D-ZYG-CH-29	Titanium	Anodised yellow	Twist Drill Zygomatic Ø2.9	10
D-ZYG-CH-29S	Titanium	Anodised yellow	Twist Drill Zygomatic Ø2.9 (Short)	10
D-ZYG-35	Titanium	Anodised yellow	Twist Drill Zygomatic Ø3.5	1
D-ZYG-35S	Titanium	Anodised yellow	Twist Drill Zygomatic Ø3.5 (Short)	1
Guided Surgery				
D-20T-GS-20	Titanium	-	Twist Drill Guided Surgery Ø1.95	1
D-20ST-GS-20	Titanium	-	Twist Drill Guided Surgery Ø1.95 Adjustable	1
D-20T-GS-23	Titanium	-	Twist Drill Guided Surgery Ø1.95	1
D-20T-GS-28	Titanium	-	Twist Drill Guided Surgery Ø1.95	1
D-20ST-GS-30	Titanium	-	Twist Drill Guided Surgery Ø1.95 Adjustable	1
D-28T-GS-20	Titanium	-	Twist Drill Guided Surgery Ø2.75	1
D-28T-GS-23	Titanium	-	Twist Drill Guided Surgery Ø2.75	1
D-28T-GS-28	Titanium	-	Twist Drill Guided Surgery Ø2.75	1
FIRST				
D-20T-32RT	Titanium	-	Twist Drill FIRST technique Ø2.0	1
D-29T-32RT	Titanium	-	Twist Drill FIRST technique Ø2.85	1
D-33T-32RT	Titanium	-	Twist Drill FIRST technique Ø3.25	1
D-35T-32RT	Titanium	-	Twist Drill FIRST technique Ø3.5	1
D-40T-32RT	Titanium	-	Twist Drill FIRST technique Ø4.0	1
EXTRA Oral				
D-20E-03F	Titanium	-	Twist Drill IE implant Ø2.0 - 3mm	1
D-20E-04F	Titanium	-	Twist Drill IE implant Ø2.0 - 4mm	1
D-20E-06F	Titanium	-	Twist Drill IE implant Ø2.0 - 6mm	1
D-30E-03F	Titanium	-	Twist Drill IE implant Ø3.0 - 3mm	1
D-30E-04F	Titanium	-	Twist Drill IE implant Ø3.0 - 4mm	1
D-30E-06F	Titanium	-	Twist Drill IE implant Ø3.0 - 6mm	1

Table 2. Bone taps

Drill code	Material	Coating (if any)	Description of product	Number of uses
External Hex				
D-TAP-IBN	Titanium	-	Tap for Hard Bone IBN	10
D-TAP-IBS	Titanium	-	Tap for Hard Bone IBS	10
D-TAP-I4B	Titanium	-	Tap for Hard Bone I4B	10
D-TAP-BA	Titanium	-	Tap for Hard Bone BA	10
D-TAP-BBBS	Titanium	-	Tap for Hard Bone BBBS	10
Tri-Nex				
D-TAP-LS-35	Titanium	-	Tap for Hard Bone Ø3.50	10
D-TAP-LS-43	Titanium	-	Tap for Hard Bone Ø4.30	10
D-TAP-LS-50	Titanium	-	Tap for Hard Bone Ø5.00	10
DC (Deep Conical)				
D-TAP-DCC30	Titanium	-	Tap for Hard Bone Ø3.00	10
D-TAP-DCC35	Titanium	-	Tap for Hard Bone Ø3.50	10
D-TAP-DCC40	Titanium	-	Tap for Hard Bone Ø4.00	10
D-TAP-DCC50	Titanium	-	Tap for Hard Bone Ø5.00	10
IT (Internal Octagon)				
D-TAP-ITC3	Titanium	-	Tap for Hard Bone Ø3.10	10
D-TAP-ITC4	Titanium	-	Tap for Hard Bone Ø4.10	10
D-TAP-ITC5	Titanium	-	Tap for Hard Bone Ø4.90	10
Tri-Nex				
D-TAP-35RT	Titanium	-	Tap for Hard Bone Ø3.50	10
D-TAP-43RT	Titanium	-	Tap for Hard Bone Ø4.30	10

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. It further adds the option for immediate placement and function on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.

Indications for use of our cylindrical twist drills and bone taps

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

Southern Implants bone taps are indicated for pre-tapping a thread into the bone when preparing an osteotomy in dense bone, by following the drill protocols as recommended in the product catalogues, to aid in implant placement.

Contraindications

Do not use in patients:

- who are medically unfit for dental implant procedure,
- 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 or iridium.

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.

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 status.
- 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:

Southern Implants cylindrical twist 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.

- 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.
- 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.

Sterilisation

Southern Implants recommends the following procedure to sterilise the cylindrical twist drills and taps prior to re-use:

Methods to sterilise the surgical instruments:

1. Pre-vacuum Sterilisation method: Steam sterilise the drills 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 procedures

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.

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 size 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

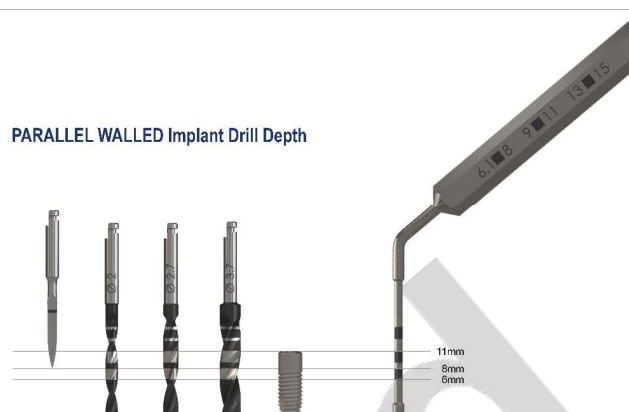


*Refer to individual product catalogues for more information:

- 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,
 - 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.
7. 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.
8. 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.

Figure 2 (DC implant used for illustration purposes)

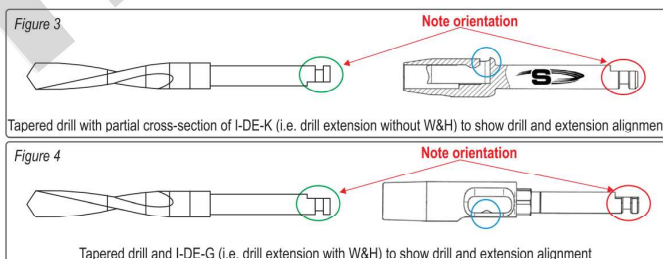


Note: Southern Implants taps feature a W&H hex on the shaft, to achieve higher torque use a converter (I-WI-C-S) over the shaft of the drill. The converter will engage the W&H hex on the tap and convert the tap to be used with a Southern Implants torque wrench. This will avoid the latch from getting stuck in the handpiece.

Drill extension

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 and 4 below:

- Drill extensions must NOT be used with $\varnothing 6$ mm and larger drills, use longer shaft drills instead.
- Drill extensions must NOT be used with Bone taps.



The orientations indicated in Figure 3 and Figure 4 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.

Some cylindrical twist drills and cylindrical bone taps can be re-used up to 10 times or when the cutting efficiency deteriorates (refer to Table 1 and 2). It is recommended to maintain a log of these drills, recording the number of uses. Prior to re-processing these components, it should be thoroughly inspected and tested to determine its suitability for re-use.

Materials:

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

Magnetic Resonance (MR) safety information

Southern Implants have 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.

Disposal

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

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.

Related Literature & Catalogues

- External Hex: CAT-2020
- Tri-Nex: CAT-2004
- Deep Conical (DC): CAT-2042
- Internal Hex (M-Series): CAT-2043
- Internal Hex (PROVATA®): CAT-2060
- IT: CAT-2005
- Zygomatic: CAT-2070
- INVERTA®: CAT-2069
- SIGuided: CAT-2068



Symbols and 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	 	 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
	* 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.				
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