SOUTHERNIMPLANTS®
Innovative Treatment Solutions

English	INSTRUCTIONS FOR USE: Southern Implants® Tapered Drills and Taps (re-useable)
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English **INSTRUCTIONS FOR USE: Southern Implants® Tapered Drills and Taps (re-useable)**

Intended use

Southern Implants® tapered drills and bone taps are intended to be used to prepare the osteotomy for implant placement. The tapered drills and bone taps are implant length specific.

Description

Southern Implants tapered drills and bone taps are as described in Table 1 and Table 2, respectively. These re-usable drills are made of stainless steel or Titanium Alloy (Grade 5) and some are coated with Titanium Nitride (TiN) or Aluminium Titanium Nitrate (AlTiN), refer to the tables below for specific details. The drills and taps are sterile.

Table 1

Drill code	Material	Coating (if any)	Final recommended Tapered: Drill for Implant Placement	Bone Condition (Soft, Medium, Dense)	Drill Identification: Laser Marked	Drill Identification: Colour ID	Number of Uses
External Hex, Internal Hex (M-series & Provata), TRI-NEX							
D-30TP-XX	Titanium Alloy	-	Ø3.0mm External Hex Implant	Dense	✓		Up to 10
D-33TP-XX	Titanium Alloy	-	Ø3.25mm External Hex Implant	Medium to Dense	✓		Up to 10
D-33TP-XX-L	Titanium Alloy	-	Ø3.25mm External Hex Implant, Longer Shaft Drill	Medium to Dense	✓		Up to 10
D-40E-04F	Titanium Alloy	-	Ø4.0mm IET/IETi External Hex Implant	Medium to Dense	✓		Up to 10
D-40TP-XX	Stainless Steel	-	Ø4.0mm External Hex Implant	Medium to Dense	✓		Up to 10
D-40TP-XX-L	Titanium Alloy	-	Ø4.0mm External Hex Implant, Longer Shaft Drill	Medium to Dense	✓		Up to 10
D-50TP-XX	Stainless Steel	-	Ø5.0mm External Hex Implant	Medium to Dense	✓		Up to 10
D-50TP-XX-L	Titanium Alloy	-	Ø5.0mm External Hex Implant, Longer Shaft Drill	Medium to Dense	✓		Up to 10
D-60TP-XX	Stainless Steel	-	Ø6.0mm External Hex Implant	Medium to Dense	✓		Up to 10
Dedicated Dense Bone Drills							
D-42TP-XX	Stainless Steel	TiN	Ø4.0mm External Hex Implant	Dense	✓		Up to 10
D-52TP-XX-L	Stainless Steel	TiN	Ø5.0mm External Hex Implant	Dense	✓		Up to 10
D-62TP-XX	Stainless Steel	TiN	Ø6.0mm External Hex Implant	Dense	✓		Up to 10
PROVATA (Internal Hex)							
D-33TP-XX	Titanium Alloy	-	Ø3.25mm Provata Implant	Medium to Dense	✓		Up to 10
D-33TP-XX-L	Titanium Alloy	-	Ø3.25mm Provata Implant, Longer Shaft Drill	Medium to Dense	✓		Up to 10
D-40TP-XX	Stainless Steel	ALTiN	Ø4.0mm Provata Implant	Medium to Dense	✓		Up to 10
D-40TP-XX-L	Titanium Alloy	ALTiN	Ø4.0mm Provata Implant	Medium to Dense	✓		Up to 10
D-50TP-XX	Stainless Steel	ALTiN	Ø5.0mm Provata Implant	Medium to Dense	✓		Up to 10
D-50TP-XX-L	Titanium Alloy	ALTiN	Ø5.0mm Provata Implant	Medium to Dense	✓		Up to 10
TRI-NEX							
Dedicated Soft Bone Drills							
DLS-35-XX	Titanium Alloy	-	Ø3.25mm Tri-Nex Implant	Soft	✓		Up to 10
DLS-43-XX	Titanium Alloy	-	Ø4.3mm Tri-Nex Implant	Soft	✓		Up to 10
DLS-50-XX	Titanium Alloy	-	Ø5.0mm Tri-Nex Implant	Soft	✓		Up to 10
DLS-60-XX	Titanium Alloy	-	Ø6.0mm Tri-Nex Implant	Soft	✓		Up to 10
Dedicated Drills							
D-L-35-XX	Stainless Steel	-	Ø3.25mm Tri-Nex Implant	Medium to Dense	✓		Up to 10
D-L-43-XX	Stainless Steel	-	Ø4.3mm Tri-Nex Implant	Medium to Dense	✓		Up to 10
D-L-50-XX	Stainless Steel	-	Ø5.0mm Tri-Nex Implant	Medium to Dense	✓		Up to 10
D-L-60-XX	Stainless Steel	-	Ø6.0mm Tri-Nex Implant	Medium to Dense	✓		Up to 10
DC (Deep Conical)							
D-DCT-30XX	Titanium Alloy	ALTiN	Ø3.0mm Deep Conical Implant	Medium to Dense	✓		Up to 10
D-DCT-35XX	Titanium Alloy	ALTiN	Ø3.5mm Deep Conical Implant	Medium to Dense	✓		Up to 10
D-DCT-40XX	Titanium Alloy	ALTiN	Ø4.0mm Deep Conical Implant	Medium to Dense	✓		Up to 10
D-DCT-50XX	Titanium Alloy	ALTiN	Ø5.0mm Deep Conical Implant	Medium to Dense	✓		Up to 10
M-Series (Internal Hex)							
D-MT37XX	Titanium Alloy	-	Ø3.7mm Internal Hex Implant	Medium to Dense	✓		Up to 10
D-MT42XX	Titanium Alloy	-	Ø4.2mm Internal Hex Implant	Medium to Dense	✓		Up to 10
D-MT50XX	Titanium Alloy	-	Ø5.0mm Internal Hex Implant	Medium to Dense	✓		Up to 10
IT (Internal Octagon)							
D-4XXT	Stainless Steel	-	Ø4.0mm IT Implant with Ø4.8mm Interface	Medium to Dense	✓		Up to 10
D-5XXT	Stainless Steel	-	Ø5.0mm IT Implant with Ø4.8mm Interface Ø5.0mm IT Implant with Ø6.5mm Interface	Medium to Dense	✓		Up to 10
D-6XXT	Stainless Steel	-	Ø6.5mm IT Implant with Ø6.5mm Interface	Medium to Dense	✓		Up to 10

INVERTA™							
D-IV37XXGS	Titanium Alloy	Anodized	Ø3.75 & Ø4.5mm DC & External Hex Implant, Guided	Medium to Dense	✓		Up to 10
D-IV45XXGS	Titanium Alloy	Anodized	Ø4.5mm DC & External Hex Implant, Guided	Medium to Dense	✓		Up to 10
D-IV50XXGS	Titanium Alloy	Anodized	Ø5.0mm DC & External Hex Implant, Guided	Medium to Dense	✓		Up to 10
D-IV60XXGS	Titanium Alloy	Anodized	Ø6.0mm DC & External Hex Implant, Guided	Medium to Dense	✓		Up to 10
D-IV37XX	Titanium Alloy	Anodized	Ø3.75 & Ø4.5mm DC & External Hex Implant, Step Drill	Medium to Dense	✓		Up to 10
D-IV45XX	Titanium Alloy	Anodized	Ø4.5mm DC & External Hex Implant	Medium to Dense	✓		Up to 10
D-IV50XX	Titanium Alloy	Anodized	Ø5.0mm DC & External Hex Implant	Medium to Dense	✓		Up to 10
D-IV60XX	Titanium Alloy	Anodized	Ø6.0mm DC & External Hex Implant	Medium to Dense	✓		Up to 10
MAX Implants (MAX, PROMAX, TRI-MAX, MAXIT)							
D-MAX6-X	Titanium Alloy		Ø6.0mm MAX External Hex Implant	Medium to Dense	✓		Up to 10
			Ø6.0mm MAX PROMAX Implant				Up to 10
D-70TP-XX	Titanium Alloy		Ø7.0mm MAX External Hex Implant	Medium to Dense	✓		Up to 10
			Ø7.0mm MAX PROMAX Implant				Up to 10
			Ø7.0mm MAX TRI-MAX Implant				Up to 10
			Ø7.0mm MAX MAXIT Implant				Up to 10
D-70TP-X-L	Titanium Alloy		All Ø7.0mm MAX Implants, Longer Shaft Drills	Medium to Dense	✓		Up to 10
D-80TP-X	Titanium Alloy		Ø8.0mm MAX External Hex Implant	Medium to Dense	✓		Up to 10
			Ø8.0mm MAX PROMAX Implant				Up to 10
			Ø8.0mm MAX TRI-MAX Implant				Up to 10
			Ø8.0mm MAX MAXIT Implant				Up to 10
D-80TP-X-L	Titanium Alloy		All Ø8.0mm MAX Implants, Longer Shaft Drills	Medium to Dense	✓		Up to 10
D-90TP-X	Titanium Alloy		Ø9.0mm MAX External Hex Implant	Medium to Dense	✓		Up to 10
			Ø9.0mm MAX PROMAX Implant				Up to 10
			Ø9.0mm MAX TRI-MAX Implant				Up to 10
			Ø9.0mm MAX MAXIT Implant				Up to 10
D-90TP-X-L	Titanium Alloy		Ø9.0mm MAX Implants, Longer Shaft Drills	Medium to Dense	✓		Up to 10

Table 2

Drill code	Material	Coating (if any)	Final recommended Tapered: Drill for Implant Placement	Bone Condition (Soft, Medium, Dense)	Drill Identification: Laser Marked	Drill Identification: Colour ID	Number of Uses
External Hex							
D-TAP-IBNT	Titanium Alloy	-	Ø3.25mm External Hex Implant	Dense	✓		Up to 10
D-TAP-IBT	Titanium Alloy	-	Ø4.0mm External Hex Implant	Dense	✓		Up to 10
D-TAP-BAT	Titanium Alloy	-	Ø5.0mm External Hex Implant	Dense	✓		Up to 10
D-TAP-BBBT	Titanium Alloy	-	Ø6.0mm External Hex Implant	Dense	✓		Up to 10
Provata (Internal Hex)							
D-TAP-IBNT	Titanium Alloy	-	Ø3.25mm Provata Implant	Dense	✓		Up to 10
D-TAP-IBT	Titanium Alloy	-	Ø4.0mm Provata Implant	Dense	✓		Up to 10
D-TAP-BAT	Titanium Alloy	-	Ø5.0mm Provata Implant	Dense	✓		Up to 10
TRI-NEX							
D-TAP-L-35	Titanium Alloy	-	Ø3.25mm Tri-Nex Implant	Dense	✓		Up to 10
D-TAP-L-43	Titanium Alloy	-	Ø4.3mm Tri-Nex Implant	Dense	✓		Up to 10
D-TAP-L-50	Titanium Alloy	-	Ø5.0mm Tri-Nex Implant	Dense	✓		Up to 10
D-TAP-L-60	Titanium Alloy	-	Ø6.0mm Tri-Nex Implant	Dense	✓		Up to 10
IT (Internal Octagon)							
D-TAP-ITT4	Titanium Alloy	-	Ø4.0mm IT Implant with Ø4.8mm Interface	Dense	✓		Up to 10
D-TAP-ITT5	Titanium Alloy	-	Ø5.0mm IT Implant with Ø4.8mm Interface	Dense	✓		Up to 10
			Ø5.0mm IT Implant with Ø6.5mm Interface				
D-TAP-ITT6	Titanium Alloy	-	Ø6.5mm IT Implant with Ø6.5mm Interface	Dense	✓		Up to 10
INVERTA™							
IV-TR-45XX	Titanium Alloy	Anodized	Ø4.5mm DC & External Hex Implant	Medium to Dense	✓		Up to 10
IV-TR-50XX	Titanium Alloy	Anodized	Ø5.0mm DC & External Hex Implant	Medium to Dense	✓		Up to 10
IV-TR-60XX	Titanium Alloy	Anodized	Ø6.0mm DC & External Hex Implant	Medium to Dense	✓		Up to 10
MAX Implants (MAX, PROMAX, TRI-MAX, MAXIT)							
D-MAX6-X	Titanium Alloy		Ø6.0mm MAX External Hex Implant	Medium to Dense	✓		Up to 10
			Ø6.0mm MAX PROMAX Implant				Up to 10
D-70TP-XX	Titanium Alloy		Ø7.0mm MAX External Hex Implant	Medium to Dense	✓		Up to 10
			Ø7.0mm MAX PROMAX Implant				Up to 10
			Ø7.0mm MAX TRI-MAX Implant				Up to 10
			Ø7.0mm MAX MAXIT Implant				Up to 10
D-80TP-X	Titanium Alloy		Ø8.0mm MAX External Hex Implant	Medium to Dense	✓		Up to 10
			Ø8.0mm MAX PROMAX Implant				Up to 10
			Ø8.0mm MAX TRI-MAX Implant				Up to 10
			Ø8.0mm MAX MAXIT Implant				Up to 10
D-90TP-X	Titanium Alloy		Ø9.0mm MAX External Hex Implant	Medium to Dense	✓		Up to 10
			Ø9.0mm MAX PROMAX Implant				Up to 10
			Ø9.0mm MAX TRI-MAX Implant				Up to 10
			Ø9.0mm MAX MAXIT Implant				Up to 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 tapered drills and bone taps

Southern Implants tapered drills are indicated for a step-wise drilling approach, when preparing an osteotomy, for tapered 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 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 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 tolearn 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 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.

Storage, cleaning & sterilisation:

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 drills 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 sterilisation to ensure sterility is maintained. Double packaging is recommended.

Sterilisation

Southern Implants recommends the following procedure to sterilise the tapered 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.

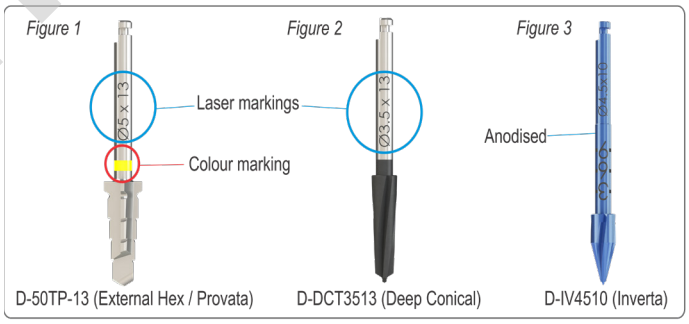
NOTE: Users in the USA must ensure that the steriliser, wrap or pouch, and all steriliser accessories are cleared by the FDA, for the intended sterilisation cycle.

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

Southern Implants provides the user with different drill options, for placement of tapered implants, depending on the bone quality. Refer to Table 1 & Table 2 for more details together with the product catalogues. The drill sizes are identified by different colour markings (paint on shaft) and / or laser markings on shaft and or anodised as shown in Figure 1,2 and 3.



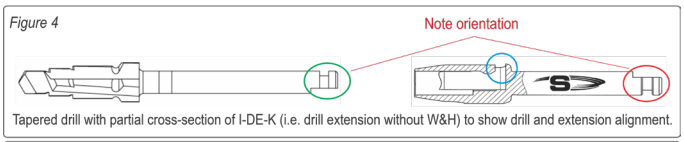
1. The tapered implants have dedicated tapered drills per implant length.
2. Tapered drills extend up to 1mm longer than the implant, when seated. Allow for this additional length when drilling near vital anatomical structures.
3. Drill at sufficient speed (800 rpm - 1200 rpm with tapered drills), with copious irrigation using sterile saline. An intermittent technique should be used to avoid overheating of the bone.
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.
5. 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.
6. Preparing the site should further involve: making sure the drill reaches full depth and / or use of the optional bone tap to pre-tap the site. Tap at low speed (25rpm), with a maximum torque of 40 Ncm. Switch the hand-piece to reverse mode for tap removal.

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

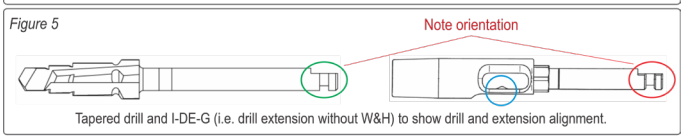
tap, the converter will engage the W&H hex on the tap and convert the tap to be used with a Southern Implants torque wrench. This will avaoid the latch from getting stuck in the handpiece.

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 4 & Figure 5 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 without W&H) to show drill and extension alignment.

The orientations indicated in Figure 4 and Figure 5 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.

Tapered drills can be used up to 10 times or when the cutting efficiency deteriorates, and bone taps up to 10 times or when the cutting efficiency deteriorates.

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

MR Safety

These products have not been tested for MRI safety, however, an analysis and review of the literature has shown that the risks of scanning a Southern Implants implant system are not of concern under the following conditions:

- a static magnetic field of 1.5 Tesla and 3 Tesla.
- a magnetic field with a field gradient of 30T/M (3000G/cm).
- a whole body specific absorption rate (SAR) of 2W/kg, for 15 minutes of scanning.

Disposal

Disposal of the device and its packaging; 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

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

Symbols and Warnings

Manufacturer: Southern Implants
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South Africa.
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CE 2797 | 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 | MD 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.