SOUTHERNIMPLANTS®
Innovative Treatment Solutions

English	INSTRUCTIONS FOR USE: Southern Implants® Tapered Drills and Taps (re-useable)
Español	INSTRUCCIONES DE USO: Southern Implants® Tapered Drills and Taps (re-useable)
Italiano	ISTRUZIONI PER L'USO: Southern Implants® Tapered Drills and Taps (re-useable)
Français	MODE D'EMPLOI : Southern Implants® Tapered Drills and Taps (re-useable)
Deutsch	GEBRAUCHSANWEISUNG: Southern Implants® Tapered Drills and Taps (re-useable)
Português	INSTRUÇÕES DE UTILIZAÇÃO: Southern Implants® Tapered Drills and Taps (re-useable)

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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.

Intended user

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

Intended environment

The tapered drills and bone taps 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 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 have a latch dimension compatible to ISO 1797. This is in order to connect the drill to the handpiece of an implant motor unit. The drills and taps are provided 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 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.
- 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 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.
- 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.
- 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.

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:

The drills 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 product must be stored in a dry place at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics.

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.

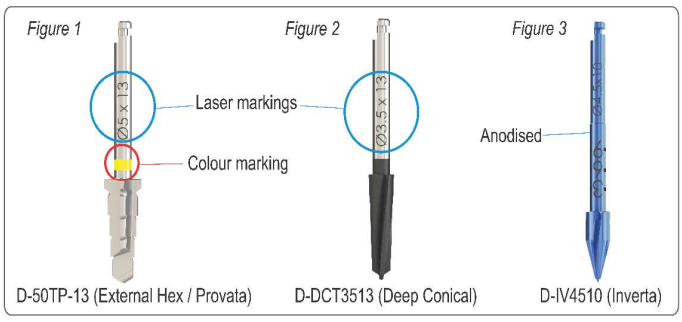
Note: Users in the USA must ensure that the steriliser, wrap or pouch, and all steriliser accessories are cleared by the FDA, for the intended sterilisation cycle.

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 procedure

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.

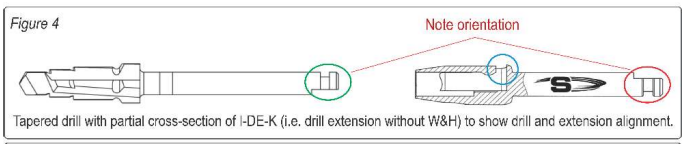
Note: Connect the drill "latch" to the handpiece. If the latch is not inserted fully into the handpiece the torque is applied to the (latch), resulting in possible twisting of the latch or damage to the handpiece. Consult the instructions for use of the handpiece to ensure proper engagement of the latch.

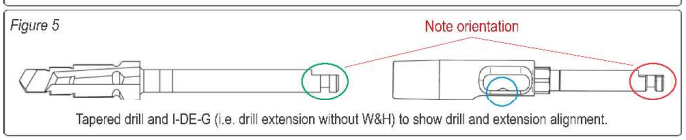
4. Use an up-and-down motion with the hand-piece, without stopping the motor. This will allow the irrigation to flush away bone debris.
5. During surgery, the clinician will be able to assess the bone quality and should use dense bone protocols when necessary to prepare the site. This is to avoid the 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.





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.

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

Clinical benefits

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).

MR Conditional

Non-clinical testing and MRI simulations were performed to evaluate the dental implant system offered by Southern Implants. Non-clinical testing demonstrates that these products are MR Conditional. A patient with an implant from a Southern Implants System can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla only
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m)
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2 W/kg and head average SAR of 3.2 W/kg, for 15 minutes of scanning (i.e., per pulse sequence) in the normal operating mode

The scanning conditions defined above will produce a maximum temperature increase of 4.9 °C in implants from Southern Implants systems after 15 minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by implants from Southern Implant System extends approximately 10 mm from this device when imaged with a gradient echo pulse sequence and a 3 Tesla MR system.

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
Basic-UDI for Reusable Instruments	600954403876

Related literature & catalogues

CAT-2004- Tri-Nex Implants Product Catalogue
CAT-2005- IT Implants Product Catalogue
CAT-2010- Osseointegrated Fixtures 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

Manufacturer: Southern Implant
1 Albert Rd, P.O Box 605 IRENE, 0062,
South Africa.
Tel: +27 12 667 1046

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

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.