SOUTHERNIMPLANTS®
Innovative Treatment Solutions

English	**INSTRUCTIONS FOR USE: Southern Implants® Cylindrical Step Twist Drills and Taps**
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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.

Intended user

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

Table 1. Twist Drills

Drill code	Material	Coating (if any)	Descripton 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	Titanuim	-	Twist Drill ø2.2 Longer shaft drill	1
D-275C-L	Titanuim	-	Twist Drill ø2.75 Longer shaft drill	1
D-350C-L	Titanuim	-	Twist Drill ø3.5 Longer shaft drill	1
D-430C-L	Titanuim	-	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	Titanuim	Anodised yellow	Twist Drill Zygomatic Ø2.7	1
D-ZYG-27S	Titanuim	Anodised yellow	Twist Drill Zygomatic Ø2.7 (Short)	1
D-ZYG-27ST-GSM	Titanuim	Anodised yellow	Twist Drill Zygomatic Ø2.7 (Medium)	1
D-ZYG-27ST-GSL	Titanuim	Anodised yellow	Twist Drill Zygomatic Ø2.7 (Long)	1
D-ZYG-29	Titanuim	Anodised yellow	Twist Drill Zygomatic Ø2.9	1
D-ZYG-29S	Titanuim	Anodised yellow	Twist Drill Zygomatic Ø2.9 (Short)	1
D-ZYG-35	Titanuim	Anodised yellow	Twist Drill Zygomatic Ø3.5	1
D-ZYG-35S	Titanuim	Anodised yellow	Twist Drill Zygomatic Ø3.5 (Short)	1
Guided Surgery				
D-20T-GS-20	Titanuim	-	Twist Drill Guided Surgery Ø1.95	1
D-20ST-GS-20	Titanuim	-	Twist Drill Guided Surgery Ø1.95 Adjustable	1
D-20T-GS-23	Titanuim	-	Twist Drill Guided Surgery Ø1.95	1
D-20T-GS-28	Titanuim	-	Twist Drill Guided Surgery Ø1.95	1
D-20ST-GS-30	Titanuim	-	Twist Drill Guided Surgery Ø1.95 Adjustable	1
D-28T-GS-20	Titanuim	-	Twist Drill Guided Surgery Ø2.75	1
D-28T-GS-23	Titanuim	-	Twist Drill Guided Surgery Ø2.75	1
D-28T-GS-28	Titanuim	-	Twist Drill Guided Surgery Ø2.75	1
FIRST				
D-20T-32RT	Titanuim	-	Twist Drill FIRST technique Ø2.0	1
D-29T-32RT	Titanuim	-	Twist Drill FIRST technique Ø2.85	1
D-33T-32RT	Titanuim	-	Twist Drill FIRST technique Ø3.25	1
D-35T-32RT	Titanuim	-	Twist Drill FIRST technique Ø3.5	1
D-40T-32RT	Titanuim	-	Twist Drill FIRST technique Ø4.0	1
EXTRA Oral				
D-20E-03F	Titanuim	-	Twist Drill IE implant Ø2.0 / 3mm	1
D-20E-04F	Titanuim	-	Twist Drill IE implant Ø2.0 / 4mm	1
D-20E-06F	Titanuim	-	Twist Drill IE implant Ø2.0 / 6mm	1
D-30E-03F	Titanuim	-	Twist Drill IE implant Ø3.0 / 3mm	1
D-30E-04F	Titanuim	-	Twist Drill IE implant Ø3.0 / 4mm	1
D-30E-06F	Titanuim	-	Twist Drill IE implant Ø3.0 / 6mm	1

Intended environment

The cylindrical twist drills and cylindrical 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 cylindrical twist drills and cylindrical bone taps, are as described in Table 1 and Table 2, respectively. These drills are made of stainless steel, Titanium (Grade 4) or Titanium Alloy (Grade 5) and some are AlTiN coated.

The drills/taps have a latch dimension compatible to ISO 1797. This is in order to connect the drill/tap to the handpiece of an implant motor unit. Drill sizes are identified by laser markings on the shaft of the drill. The drills have laser markings to indicate the drill depth.

Cylindrical twist drills and taps indicated in Table 1, are provided sterile:

- Twist drills indicated, with 1 Number of uses is for single use only
- Taps indicated with 10 Number of uses, can be used up to 10 times or when the cutting efficiency deteriorates.

Table 2. Bone taps

Drill code	Material	Coating (if any)	Descripton of product	Number of uses
External Hex				
D-TAP-IBN	Titanuim	-	Tap for Hard Bone IBN	Up to 10
D-TAP-IBS	Titanuim	-	Tap for Hard Bone IBS	Up to 10
D-TAP-I4B	Titanuim	-	Tap for Hard Bone I4B	Up to 10
D-TAP-BA	Titanuim	-	Tap for Hard Bone BA	Up to 10
D-TAP-BBBS	Titanuim	-	Tap for Hard Bone BBBS	Up to 10

Tri-Nex				
D-TAP-LS-35	Titanuim	-	Tap for Hard Bone Ø3.5	Up to 10
D-TAP-LS-43	Titanuim	-	Tap for Hard Bone Ø4.3	Up to 10
D-TAP-LS-50	Titanuim	-	Tap for Hard Bone Ø5.0	Up to 10
DC (Deep Conical)				
D-TAP-DCC30	Titanuim	-	Tap for Hard Bone Ø3.0	Up to 10
D-TAP-DCC35	Titanuim	-	Tap for Hard Bone Ø3.5	Up to 10
D-TAP-DCC40	Titanuim	-	Tap for Hard Bone Ø4.0	Up to 10
D-TAP-DCC50	Titanuim	-	Tap for Hard Bone Ø5.0	Up to 10
IT (Internal Octagon)				
D-TAP-ITC3	Titanuim	-	Tap for Hard Bone Ø3.3	Up to 10
D-TAP-ITC4	Titanuim	-	Tap for Hard Bone Ø4.1	Up to 10
D-TAP-ITC5	Titanuim	-	Tap for Hard Bone Ø4.9	Up to 10
FIRST				
D-TAP-35RT	Titanuim	-	Tap for Hard Bone Ø3.5 FIRST Technique	Up to 10
D-TAP-43RT	Titanuim	-	Tap for Hard Bone Ø4.3 FIRST Technique	Up to 10

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, medium 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 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 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. All components, instruments and tooling used during the clinical or laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components or equipment.

Post-surgery

Regular patient follow-up, and proper oral hygiene must be achieved to ensure favourable long-term results.

Storage, cleaning & sterilisation

These devices 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 devises must be stored in a dry place at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics.

Single use devices:
Do not reuse devices indicated for single use. (Use the device prior to the expiration date).
Do not reuse implants, single use drills, cover screws, temporary abutments and abutments. Reusing these components may result in:

- Damage on the surface or critical dimensions, which may result in performance and compatibility degradation.
- Adds the risk of cross-patient infection and contamination if single-use items are reused.

Southern Implants does not accept any responsibility for complications associated with reused components.

Reusable devices:
Prior to re-using this device, it needs to be inspected, if there are signs of visible corrosion, deformed or twisted connections, dull cutting edges, expected wear and damage, this device shall be exposed of. After inspection, and re-use seems fit, the devises are cleaned, disinfected and sterilised.

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 into the storage container. If additional drying is necessary, dry in a clean location. Moisture on these devices can cause corrosion and deterioration of the cutting edges.
- **Inspection:** Do a visual inspection of the items to check for any damage.
- **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 instruments prior to use/re-use:

Methods to sterilise these devices:

1. Pre-vacuum Sterilisation method: Steam sterilise the instruments 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 procedure

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 product 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. Refer to individual product catalogues for more information.

Figure 1

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.

Note: Connect the drill/tap 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.

2. Drill at sufficient speed (between 1000-1500rpm for Cylindrical Drills), under constant irrigation with sterile saline.
3. Use an up-and-down motion with the handpiece, 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-20 for External Hex, Internal Hex, IT and TRI-Nex,
   - I-DG-24 for External Hex, Internal Hex, IT and TRI-Nex,
   - I-ZYG-DG-1 for Zygomatic Implants,
   - I-DG-DC for DC implants.

Figure 2 (DC implant used for illustration purposes)

6. 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. It is recomended to undersize the osteotomy in soft bone, and use a bone tap in dense bone.
7. 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 handpiece to reverse mode to remove the tap.

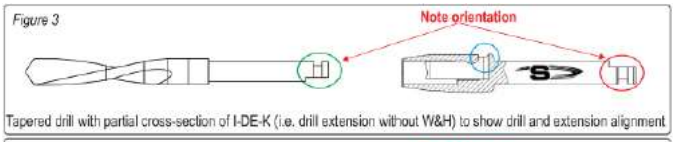
Note:

- 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 avoid the latch from getting stuck in the handpiece.
- Avoid lateral pressure (bending) on the drills during drilling procedures.
- Lateral pressure to the drill can cause drill fracture.
- Verify the drill is securely locked into the handpiece before drilling procedure starts.

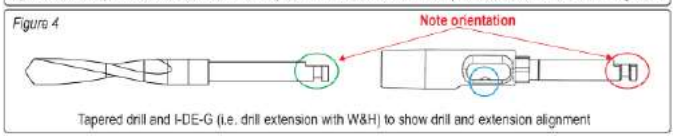
Drill extension

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 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

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 (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.

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, Titanium (Grade 4) 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-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

CE 2797

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.