SOUTHERNIMPLANTS®
Innovative Treatment Solutions

English	INSTRUCTIONS FOR USE: Southern Implants® Deep Conical Implants
Español	INSTRUCCIONES DE USO: Southern Implants® Deep Conical Implants
Italiano	ISTRUZIONI PER L'USO: Southern Implants® Deep Conical Implants
Français	MODE D'EMPLOI : Southern Implants® Deep Conical Implants
Deutsch	GEBRAUCHSANWEISUNG: Southern Implants® Deep Conical Implants
Português	INSTRUÇÕES DE UTILIZAÇÃO: Southern Implants® Deep Conical Implants

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Intended use

The devices are intended to treat partially or fully edentulous patients eligible for placement of one or more dental implants as a means of fixing a permanent or removable single crown, partial or full-arch dental prosthesis in the upper or lower jaw. The devices allow for immediate or delayed prosthetic restoration based on the user's evaluation of the patient's eligibility.

Intended user

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

Intended environment

The implants are intended to be used in a clinical environment such as an operating theater or a dentist consultation room.

Intended patient population

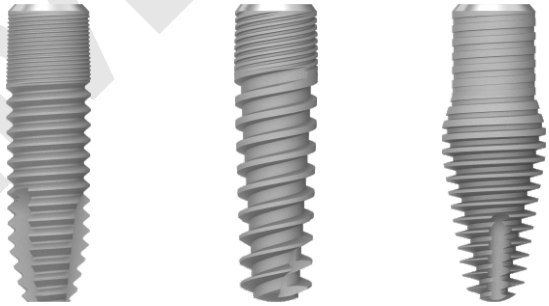
This device is used in the dental restoration of partially or fully edentulous patients in the upper or lower jaw. Restorations may comprise single teeth, partial or full bridges, and may be fixed or removable.

Description

The Deep Conical implant is a self-tapping implant made of commercially pure special Grade 4 Titanium (UTS ≥900 Mpa). Implants are available with either a tapered or parallel walled body shape. Micro-threads on the implant neck, maximize bone implant contact and optimally distribute load in the critical cortical bone region. All implants are surface-roughened up to the collar using Southern Implants' proven surface. The surface has a S_a value of 1.4 microns. The Deep Conical implants are available in the angulated platform Co-Axis® design, tapered and parallel walled body shape. With a built-in platform angulation of 12°, this design enables tilting of the implant without compromising the restorative emergence angle. Cover screws and healing abutments are sold separately.

DEEP CONICAL — **Straight**

	CODE	LENGTHS	Cylindrical or Tapered
Ø3.0	DCT30	9 / 11 / 13	T
	DCC30	8/11/ / 13 / 15	C
Ø3.5	DCT35	8 / 9 / 11 / 13 / 15	T
	DCC35	8 / 9 / 11 / 13 / 15	C
Ø4.0	DCT40	6 / 8 / 9 / 11 / 13 / 15	T
	DCC40	6 / 8 / 9 / 11 / 13 / 15	C
Ø5.0	DCT50	9 / 11 / 13 / 15	T
	DCC50	9 / 11 / 13 / 15	C



DEEP CONICAL — **INVERTA®**

	CODE	LENGTHS	Cylindrical or Tapered
Ø3.5 - Ø4.5	IV-DC35-45	8 / 10 / 11 / 13 / 15	T
Ø4.0 - Ø5.0	IV-DC40-50	10 / 11 / 13 / 15	T
Ø5.0 - Ø6.0	IV-DC50-60	10 / 11 / 13 / 15	T

DEEP CONICAL — **Co-Axis®**

* Prosthetic platform angled at 12°

	CODE	LENGTHS	Cylindrical or Tapered
Ø3.5	DCT35xx-12d	8 / 9 / 10 / 11 / 13 / 15	T
	DCC35xx-12d	8 / 9 / 10 / 11 / 13 / 15	C
Ø4.0	DCT40xx-12d	8 / 9 / 10 / 11 / 13 / 15	T
	DCC40xx-12d	8 / 9 / 10 / 11 / 13 / 15	C
Ø4.0	DCT50xx-12d	8 / 9 / 10 / 11 / 13 / 15	T
	DCC50xx-12d	8 / 9 / 10 / 11 / 13 / 15	C

DEEP CONICAL — **INVERTA®**

	CODE	LENGTHS	Cylindrical or Tapered
Ø3.5 - Ø4.5	IV-DC3512D-45	11 / 13 / 15	T
Ø4.0 - Ø5.0	IV-DC4012D-50	11 / 13 / 15	T

Indications for use

Southern Implants dental implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols:

- Replacing single and multiple missing teeth in the mandible and maxilla.
- Placement in extraction sites and in situations with a partially or completely healed alveolar ridge.
- Especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective.
- Immediate loading in all indications, except in single tooth situations on implants shorter than 8mm or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate.
- The intended use for 3.0 Deep Conical implants is limited to replacement of maxillary lateral incisors and mandibular incisors
- INVERTA® implants are indicated for immediate restoration of single implants in the anterior maxilla.

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.
- For short implants, clinicians should closely monitor patients for any of the following conditions: peri implant bone loss, changes to implant's response to percussion, or radiographic changes in bone to implant contact along the implant's length. If the implant shows mobility or greater than 50% bone loss, the implant should be evaluated for possible removal. If the clinicians choose a short implant, then clinicians should consider a two-stage surgical approach, splinting a short implant to an additional implant, and placement of the widest possible fixture. Allow longer periods for osseointegration and avoid immediate loading.

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.
- Minimising 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.

Pre-operative examination and planning

A full medical and dental history must be taken, with emphasis on the presence of soft and or hard tissue pathology. The patient must have clinically symptom-free sinuses and no pathology in surrounding bone or soft tissue.

It is recommended that a CT scan and or CBCT analysis be performed as part of the planning process in order to;

- Detect the presence of any pathology in the maxillary sinuses.
- Bone volume and condition.
- Jaw relationships.
- Choose an appropriate size implant for the amount of bone available, without violating the biological width, and evaluate sufficient bone volume surrounding the implant body. In dense bone, use new drills and profuse irrigation. In low-density bone, it is recommended to undersize the osteotomy by drilling with a smaller final drill (i.e. If placing a diameter 4.0mm implant, final shaping drill would be 3.5mm.

Storage, cleaning & sterilisation

The implants, cover screws and healing abutments are supplied sterile (sterilised by gamma irradiation) and intended for single-use prior to the expiration date (see packaging label). 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.

Do not reuse implants, 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.

Packaging & precautions to maintain the sterility of the implant

Implants are packaged as follows:

1. An outer package consisting of a rigid, clear box which acts as protection for the inner package.
2. The inner package consisting of a blister pack (clear plastic-formed blister base with a TYVEK "peel-back" lid)
3. Within the inner package there is a hollow tube which contains one implant suspended from a titanium ring, this ensures the implant never touches the inside of the plastic tube.
4. Labelling information is located on the surface of the peel-back lid and on the outside of the rigid box

Care must be taken to maintain the sterility of the implant by proper opening of the packaging and handling of the implant.

1. Open the implant package in the non-sterile field, with non-sterile gloves, tear the address label to open the box.
2. With non-sterile gloves remove the inner blister pack. Do not place the plastic box or blister pack-lid onto the sterile field. The contents of this inner package are sterile.
3. The sealed blister is to be opened by an assistant (with nonsterile gloves): remove the TYVEK lid and drop or place the sterile tube onto the sterile field, open the tube cap and attach the implant placement tool onto the implant and carefully remove from the sterile tube. Do not touch the sterile implant.

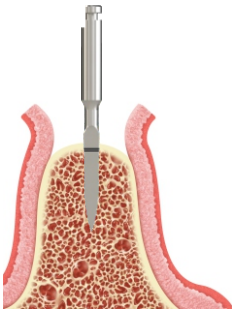
Other sterile components are packed in a peel pouch or blister base with a "peel-back" lid. Labelling information is located on the bottom half of the pouch, inside the packet or on the surface of the peel-back lid. Sterility is assured unless the pouch is damaged or opened.

Non-sterile components are supplied clean but not sterile in a peel pouch or blister base with peel-back lid. Labelling information is located on the bottom half of the pouch, or on the surface of the peel-back lid.

SURGICAL PLACEMENT

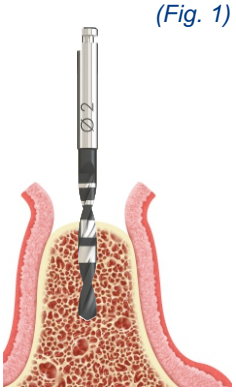
PARALLEL WALLED IMPLANTS

Step 1: Initiate the osteotomy (*Fig. 1*)
Note: It is recommended to raise a full-thickness mucoperiosteal flap.
The 3Spade drill (D-3Spade-1.8M) (*Fig. 4A*) is used to initiate the osteotomy by perforating the cortical plate at the desired location.


(*Fig. 1*)

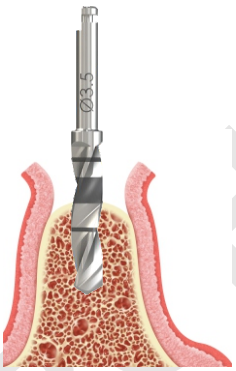
All drilling should be performed at a speed of 1000-1500 rpm with copious irrigation. An intermittent technique should be used to avoid overheating of the bone.

Step 2: Pilot drilling – Ø2mm Twist Drill (*Fig. 2*)
Drill with the Ø2mm twist pilot drill (D-DC20) (*Fig. 4B*) to the implant length corresponding to the laser markings on the twist drills and depth gauge (*Fig. 4C*).
Note: Depth should allow the implant to inserted level or slightly submerged in the surrounding bone.
To verify the alignment with adjacent teeth/implants, insert the direction indicator (I-DI) (*Fig. 4D*). A radiograph is taken at this point to verify the depth and angulation. If the drilling direction is incorrect, start a new direction with the Ø2mm pilot drill.



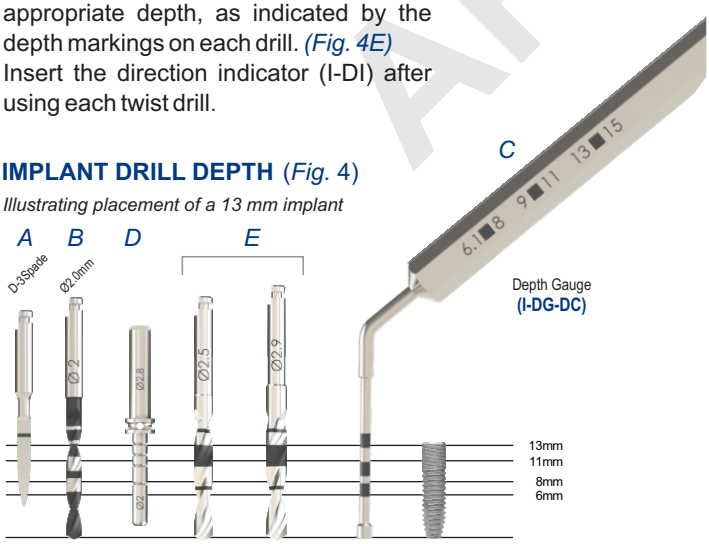
(*Fig. 2*)

Step 3: Gradually enlarge the osteotomy *(Fig. 3)*
Repeat Step 2 for each consecutive twist drill in the drill sequence corresponding to the selected implant. Drill to the appropriate depth, as indicated by the depth markings on each drill. *(Fig. 4E)*
Insert the direction indicator (I-DI) after using each twist drill.



(*Fig. 3*)

IMPLANT DRILL DEPTH (*Fig. 4*)
Illustrating placement of a 13 mm implant



Note
Caution should be taken to not over prepare the implant site, especially for shorter length implants (9mm and shorter).
With a probe, check the soft tissue height, prepare final step at least 1 mm subcrestal. Depending on the gap between planned implant and buccal bone plate, deeper countersinking can be appropriate.

SURGICAL PLACEMENT

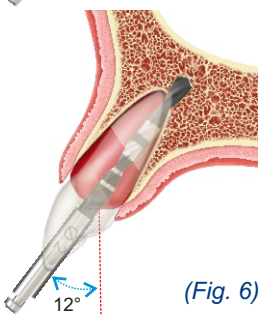
TAPERED & CO-AXIS® IMPLANTS

Step 1: Initiate the osteotomy
As per Step 1 (*Fig. 1*).

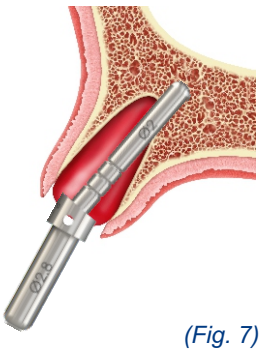
Step 2: Pilot drilling – Ø2mm Twist Drill
As per Step 2 (*Fig. 2*). **Tapered Implants**

Pilot drilling: Ø2mm Twist Drill (Co-Axis® implants)
Drill in the planned angled direction to the appropriate depth, as indicated by the depth markings on the Ø2mm twist drill (D-DC20). If an anterior implant is being placed, ***align the drill to the incisal edge of the adjacent tooth.*** (*Fig. 5 & 6*).
With the 12° Co-Axis® angulation, the screw access hole will come out on the palatal side if aligned correctly.
If the osteotomy is angulated too much to the palatal side (e.g. normal direction when preparing for a screw retained restoration) there is a risk of a sub-optimal restoration angle, with soft and hard tissue being compromised on the palatal side. Insert the direction indicator (I-DI-12d) (*Fig. 7*).
A radiograph is taken at this point to verify the depth and angulation. If the drilling direction is incorrect, start a new direction with the Ø2mm pilot drill.


(*Fig. 5*)

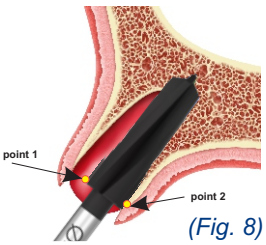


(*Fig. 6*)



(*Fig. 7*)

Step 3: Gradually enlarge the osteotomy
The Deep Conical tapered drills are length and diameter specific. Use the length and diameter drill corresponding to the implant that is selected. Widen the osteotomy intermittently to the desired diameter. *(Fig. 9E)*.
Follow the recommended drill protocols for soft, medium and dense bone by referring to catalogue.
Final drill position for Co-Axis® implants. *(Fig. 8)*

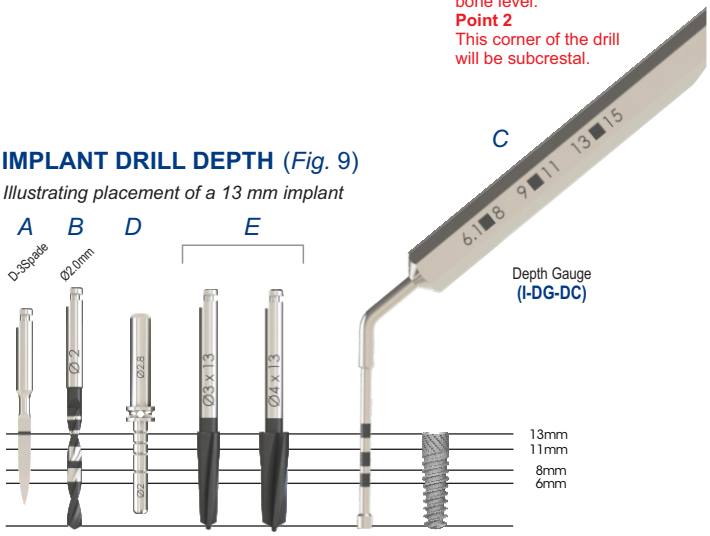


(*Fig. 8*)

***Final Tapered Drill Position** (Co-Axis)

PLEASE NOTE:
Point 1
This corner of the drill is to be at bone level.
Point 2
This corner of the drill will be subcrestal.

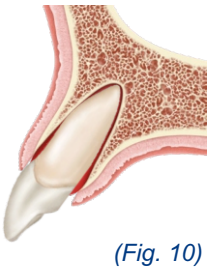
IMPLANT DRILL DEPTH (*Fig. 9*)
Illustrating placement of a 13 mm implant



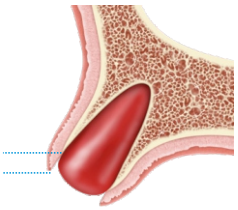
SURGICAL PLACEMENT

INVERTA® STRAIGHT & CO-AXIS® IMPLANTS

Step 1: Extraction (*Fig. 10*)
When extracting a tooth for immediate implant placement it is important to do the extraction atraumatically to keep the buccal bone plate intact. Preferably, a periotome should be used to carefully loosen the tooth from the periodontium. After extraction, evaluate the buccal bone plate.
If the bone is intact, evaluate the buccal soft tissue height. This will give you an indication of the vertical placement *(Fig. 11)*.
Carefully curettage the socket and remove all infected tissue where necessary.
If the bone is not intact it is recommended to abort the procedure and let the socket heal with or without augmentation material.



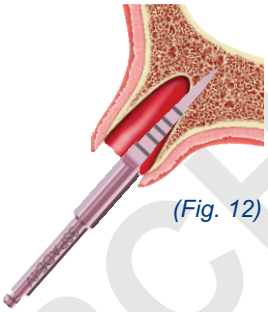
(Fig. 10)



(Fig. 11)

Step 2: Initiate the Osteotomy
Select the right implant diameter and length. Inverta has a larger diameter apical design for good primary stability. The coronal part has minor diameter for 3 main purposes.

1. Greater distance between buccal bone-wall and implant for undisturbed blood supply to the surrounding bone.
2. Greater distance mesial-distal. Plan the osteotomy for minimum 2mm bone buccal lingual and minimum 1.5 mm mesial distal bone between implant and adjacent teeth and 3 mm in-between implants.
3. Emergence profile design. Place Implant 3-4mm below the buccal CEJ or minimum 1 mm sub crestal depending on soft tissue height and distance to buccal wall.

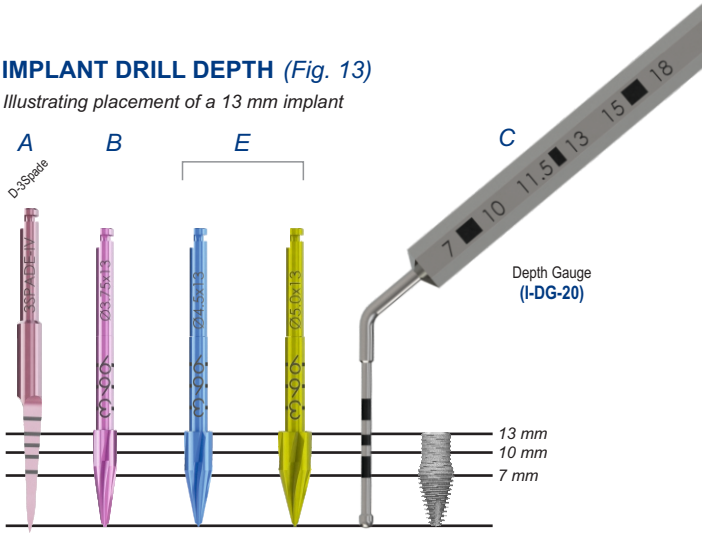


(Fig. 12)

The 3-Spade drill (D-3Spade-IV) *(Fig. 12)* is used to initiate the osteotomy. In an extraction socket, initiate drilling on the palatal wall approximately 1/3 from the apex. For an anterior implant being placed, ***align the drill to the incisal edge of the adjacent tooth.***
With the 12 degree Co-Axis® angulation, the screw access hole will end up on the palatal side in the area of the cingulum if aligned correctly. If the osteotomy is angulated too much to the palatal side (e.g. normal direction when preparing for a screw retained restoration) there is a risk of sub-optimal restoration angle, with soft and hard tissue being compromised on the palatal side.
If possible, it is recommended to drill 1 mm deeper compared to implant length, enabling a freedom of correcting the Co-Axis angulation

IMPLANT DRILL DEPTH *(Fig. 13)*

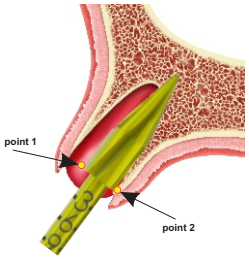
Illustrating placement of a 13 mm implant



Step 3: Gradually enlarge the osteotomy
(Ø3.75mm - Ø5.0mm Tapered Drills)
The Inverta tapered shaping drills are length and diameter specific. Drill in the planned direction to the appropriate depth, as indicated by the depth markings on the drill *(Fig. 13)* .

Note: Vertical positioning is dependent on ECJ on neighboring teeth, soft tissue height and the jump gap between the buccal wall and implant.

In soft bone the osteotomy can be under-prepapared for higher primary stability. If a 4,5mm apical diameter Inverta is being placed, one can consider the 3.75mm tapered drill as final drill diameter. The Inverta implant is however designed to reach high primary stability using the dedicated final drill. In most bone qualities the Inverta implant will show high primary stability enabling immediate load with predictable outcome.
Final drill position for Co-Axis® implants. *(Fig. 14)*



(Fig. 14)

***Final Tapered Drill Position** (Co-Axis)

PLEASE NOTE:

Point 1
This corner of the drill is to be at bone level.

Point 2
This corner of the drill will be subcrestal.

Clinical benefits associated with DC implants
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.

Materials
Implant: Commercially pure titanium (grade 4, ASTM F67 and ISO5832-2, UTS≥ 900MPa).

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 tensile or compressive 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 special gradient magnetic field of 4,000 gauss/cm (40T/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 do 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 General Dental Implants	600954403869

Related literature & catalogues
CAT-2042 - Deep Conical Implants Product Catalogue

Symbols and Warnings

Manufacturer: Southern Implants
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.