SOUTHERNIMPLANTS®
Innovative Treatment Solutions

English **INSTRUCTIONS FOR USE: Southern Implants® Osseointegrated Fixtures Implants**

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Intended use

The implants are placed in bone and are intended to osseointegrate to provide an attachment for an external aesthetic restoration / prosthesis. The device provides a solution for the prosthetic restoration of a cosmetic defect when other means (such as adhesives or suction) are inadequate to retain the prosthesis.

Description

Southern Implants manufactures implants from biocompatible commercially pure titanium. The surface is enhanced with abrasion (grit-blasting), resulting in a pure and consistent surface. The restorative components are manufactured from titanium, titanium alloy, gold alloy and a variety of polymers.

The IET and IE are ultra-short pure titanium implants. The IET4 is Ø4.5 mm by Ø4.1 mm in length. It is significantly tapered, for the purpose of achieving good primary stability. The IE is Ø3.75mm and available in 3 mm, 4 mm and 6 mm lengths.. It has a wide flange to prevent intracranial penetration from trauma. The ultra-short implants can usually be used for all craniofacial defects where there is insufficient bone volume for longer implants.
In large craniofacial defects bone volume can often be found for longer implants.

Indications for use

Southern Implants Osseointegrated Fixtures are indicated for the attachment of an external aesthetic restoration / prosthesis for the restoration of a physical defect when other means of attachment are inadequate. These devices are indicated for use in the maxillo-cranofacial region (including the ear, nose and eye regions).

Intended user

Maxillo-facial Surgeons, Periodontists, Prosthodontists and other appropriately trained and experienced implant users.

Implants are pre mounted and available in lenghts of:

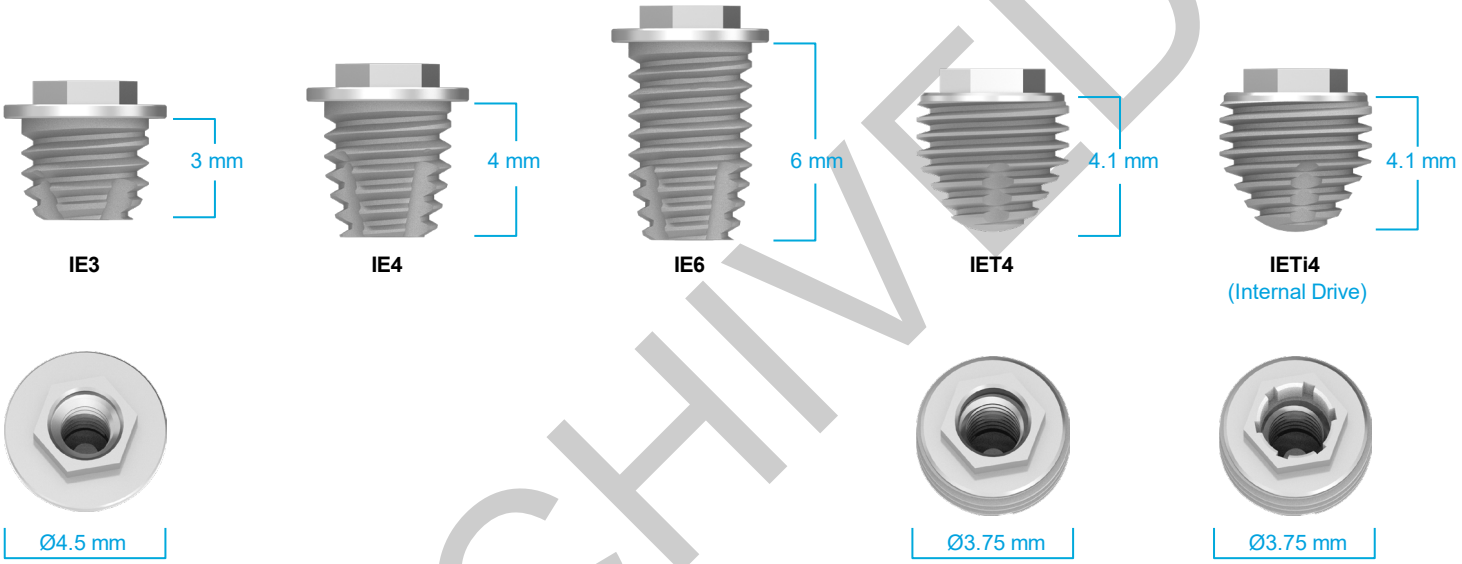
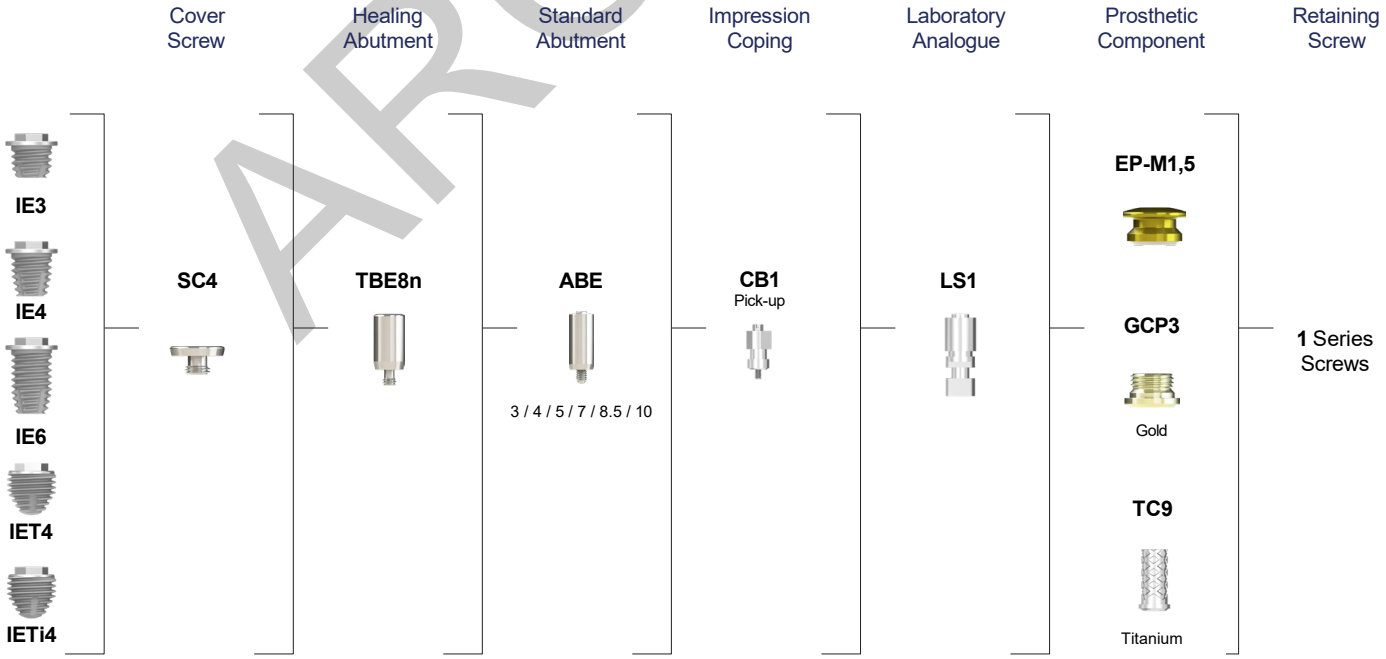


Figure 1: Osseointegrated Implant prosthetic flowchart



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 restoration of patients requiring implants attached of an external aesthetic restoration/prosthesis restored.

Pre-operative procedures
Planning and precautions
Thorough screening of prospective implant candidates must be performed. Elicit and record a comprehensive medical history and consider the relevance of that information to the individual case. Visual inspection and radiographs are essential to determine anatomical landmarks and adequacy of bone. Ensure the patient has realistic expectations of the implant and the prosthetic treatment. The process of the therapy and possible morbidities should be adequately discussed.

A systematic and coordinated plan delineating the responsibilities of each member of the team should be developed and followed. During the planning phase it is important to determine if the available bone dimensions are adequate for implant placement and to confirm that the available prosthetic space is sufficient to accommodate the proposed abutment and final restoration. Minimizing the trauma to the host tissue increases the potential for successful osseointegration.

Anatomical considerations ears
Auricular remnants can be removed, but it is important to ensure the patient accepts this knowing it is irreversible.

Eyes, noses and other craniofacial defects
The bone encountered in these applications is irregularly shaped. The implants must be placed using the available bone, but it is also important to consider the position of the implants for the prosthetics. The implants should emerge in a place where the attachment can be concealed within the bulk of the prosthesis, and should not make it difficult for the patient to detach.

Clinical benefits
Patients can expect to have an external aesthetic restoration/prosthesis restored.

Storage, cleaning and 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 antd 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 and 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.

Contraindications
Do not use in patients:
- who are medically unfit for 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 and sinus pathology.

Warnings
THESE INSTRUCTIONS ARE NOT INTENDED AS A SUBSTITUTE FOR ADEQUATE TRAINING.
- For the safe and effective use of 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 attempting 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 history.
- visual and radiological inspection to determine adequate bone dimensions and anatomical landmarks.
- proper pre-operative planning with a good team approach between well trained surgeons, restorative 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.

Surgical and prosthetic procedure

Implant placement planning must be done by the full team responsible for the complete treatment of the patient. A thorough examination, including etiology of the tissue, should be done. All procedures and possible morbidities must be described to the patient. At least two implants must be used per prosthetic rehabilitation. Avoid large cantilevers in the prosthesis. Implants should be placed at least 10mm apart. Implant positioning is important. As much as it depends on the availability of bone, it must also be appropriate for the prosthesis – implants must emerge in the bulk of the prosthesis where the attachment can be concealed.

Prosthetic ears
Two implants is usually sufficient for prosthetic ear attachment. Place implants parallel to each other. The standard abutments can be used and a bar can be constructed to fit within the anti-helix of the ear.

Prosthetic eyes, noses and other craniofacial epitheses
Other craniofacial epitheses usually require three (or more) implants for adequate support. It can be difficult to place implants in parallel, in which case magnetic abutments from Technovent can be used (see www.technovent.com).

Table A

Defect Location	Implant	Abutment
Ear	IE IET	Standard abutment + Bar
Eyes or nose	IE IET	Magnetic abutment (www.technovent.com)
Large craniofacial / midfacial	IE IET	Standard abutment + Bar or Magnetic abutment (www.technovent.com)

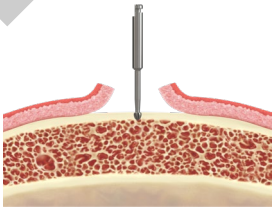
Step 1: Initiate the osteotomy *(Fig. 1)*

NOTE: It is recommended to raise a full-thickness flap.

The round burr (D-RB-MS) is used to initiate the osteotomy by perforating the cranial bone at the desired location.

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.

Fig. 1

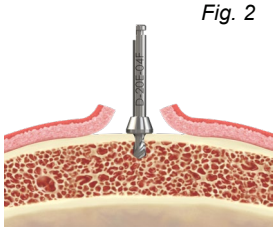


Step 2: Pilot drilling *(Fig. 2)*

The pilot hole is then created using a Ø2.0 mm dedicated drill. Drill in the planned direction to the appropriate depth. Drill depth is controlled by the flange on the drill.

NOTE: depth should allow implant to be inserted level with or slightly submerged in surrounding marginal bone.

Fig. 2



Step 3: Gradually enlarge the osteotomy *(Fig. 3 and 4)*

The Osseointegrated Fixtures' 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. The final drill will then be used to prepare the site for the implant.

NOTE: the final drill need not be used in soft bone.

WARNING: the total implant length is reached when the drill flange touches the bone surface. The drill will continue drilling (with higher resistance) and countersink the implant. This will drill deeper than the length of the implant so ensure there are no sensitive anatomical landmarks in reach of the drill.

Fig. 3

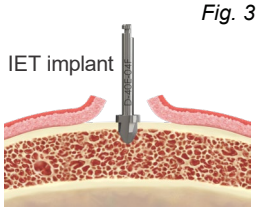
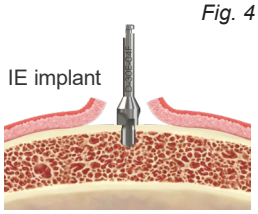


Fig. 4



Step 4: Implant placement *(Fig. 5 and 6)*

A) The **IET** and **IE** implants are supplied with a Fixture Mount.

Connect the handpiece insertion tool (I-CON-X) to the handpiece. Engage the implant mount, and carefully remove the implant from the sterile vial.

Insert the implant at low speed (15-20 rpm) without irrigation.

B) The **IETi** implants are placed with an insertion tool, that fits into the implant (spline in internal thread).

Connect the insertion tool (I-HID-S / M / L) to the handpiece, and carefully remove the implant from the sterile vial. The insertion tool in the implant must be fully engaged before torque is applied, to prevent any damage.

Alternatively, the wrench insertion tool (I-WIID-S / L) can be connected to the ratchet wrench (I-TWS), with wrench insert converter (I-WI-SS), and used to the implant from its packaging.

Insert the implant at low speed (15-20 rpm) without irrigation.

Fig. 5

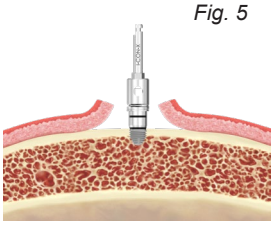


Fig. 6

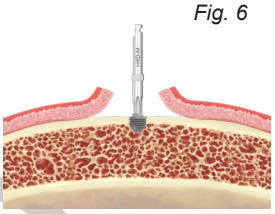
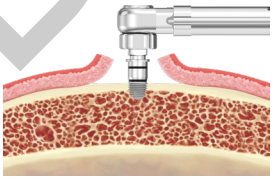


Fig. 7



Step 6: Fully seat the implant *(Fig. 7 and 8)*

The implant is placed such that the platform of the IET implant, or the bottom of the flange for the IE implant, is flush with the bone.

The ratchet and torque attachment wrench (I-TWS with I-TWS-B45 / B100), in combination with the converter (I-WI-SH) may be used for final seating of the implant. For insertion torques above 50 Ncm, this manual wrench is indicated. See table Below.

WARNING: do not continue inserting the IE implants once the flange hits the bone – this can cause the screw thread in the bone to strip, reducing primary stability.

NOTE: if final stability is less than 10 Ncm remove implant and prepare a new implant site in adjacent bone with a lower torque setting on the motor unit.

Fig. 8

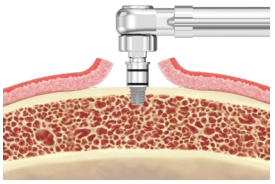
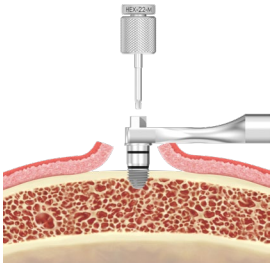


Table B: Torque values to seat implant

Implant	Medium-soft bone	Hard bone
IE3, IE4	10-20 Ncm	30-50Ncm
IE6	20-30 Ncm	60-70 Ncm
IET4	10-20 Ncm	40-50 Ncm

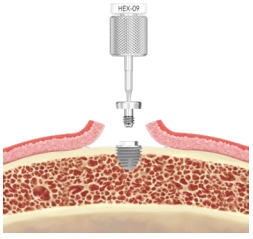
Fig. 9



Step 7: fixture mount removal *(Fig. 9)*

Undo the fixture mount screw (TSHZ3) with a 1.22 hex handpiece bit (I-HHD-22M/L) or hand-held driver (I-HD-M/L) and remove the fixture mount. Use of the fixture mount spanner (I-SP-X) is recommended to avoid loosening the implant.

Fig. 10



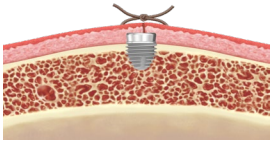
Two-stage procedure *(Fig. 10, 11 , 12 and 13)*

After the implant is fully seated in the osteotomy, place the cover screw (SC4) with a selfgripping 0.9 hex cover screw driver (I-CS-HD).

NOTE: tighten to 10-15 Ncm.

Reposition the flap margins together and suture closed *(Fig. 11)*

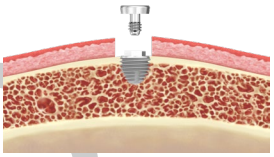
Fig. 11



After the recommended healing period, in a second surgery, remove the cover screw *(Fig. 12)*.

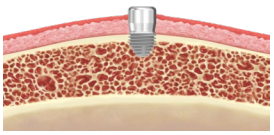
Exposure of the cover screw can be done either with a tissue cutter (I-TC1) or a mid-crestal incision using a scalpel. Locate the cover screw by probing the soft tissue.

Fig. 12



Place the temporary healing abutment using the 1.22 hex hand-held (I-HD-S / M / L) driver or the permanent abutment using the abutment (I-AD) driver in the implant to approximately 10-15 Ncm (hand tightened) *(Fig. 13)*. Ensure the correct abutment length is chosen such that the abutment protrudes the correct amount from the skin. The standard abutment (ABE) can be used for constructing a bar, or Titanmagnetics abutment can be used.

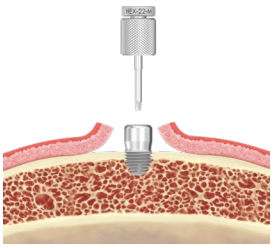
Fig. 13



The impression can be taken at the abutment level using the appropriate impression coping.

One-stage procedure *(Fig. 14 and 15)*

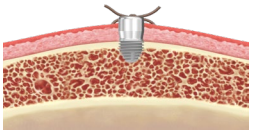
Fig. 14



Place the selected healing abutment or appropriate definitive abutment with a 1.22 hex hand held (I-HD-S / M / L), handpiece (I-HHD-22S / M / L) or wrench insert (I-WI-22S / M / L) driver.

NOTE: tighten to 10-15 Ncm.

Fig. 15



Arrange the flap margins around the healing abutment for a tight seal and suture.

The impression can be taken at the abutment level using the appropriate impression coping.

Post-placement procedures

Patient home-care

Patients must be instructed to clean and monitor the peri-implant area daily once the dressing is removed – it is of paramount importance to ensure soft tissue health. This can be done during their daily bath or shower. A soft cleaning brush or alcohol free wipes can also be used. Tissue health must be reviewed at check-ups.

Table C: Recommended healing periods

ONE-STAGE	TWO-STAGE
Healing period = 3-4 months	Healing period = 4-6 months
Auricular defects: Good bone quality > 3 mm thick for all implants	Auricular defects: Good bone quality < 3 mm
Healthy soft-tissue	Orbital, nasal and other craniofacial defects
	Compromised or soft bone
	Irradiated bone
	Compromised soft-tissue condition

Table D: Recommended healing periods

	ONE-STAGE	TWO-STAGE
Surgery		First
Leave to osseointegrate with cover screw		3 - 4 months
Surgery	First	Second
Apply a pressure gauze dressing	Immediately after surgery	Immediately after 2nd surgery
Check dressing, remove or reapply for another week	1-2 weeks after surgery	1-2 weeks after surgery
Clean around the implantabutment area	Daily by patient	Daily by patient
Take impression of healed implant site	3 months after surgery	± 1 month after surgery
Total time to prosthesis fitment	3-4 months	4-6 months

Post-placement precautions MRI

Any bar framework construction, magnetic abutments or any attachment besides the Southern Implants' implants and abutments (or cover screws) should be removed before MRI scanning. The implant and abutment may produce a small artefact in MRI scans.

Radiation

If radiation treatment is scheduled after placement of an abutment it is recommended that the abutment is removed and replaced with a cover screw to allow healing before radiation is performed.

Trauma

Patients should be aware that implants are susceptible to traumatic loss and they should be instructed to take care when participating in rough or rigorous physical activity.

Side effects

Potential side effects and temporary symptoms: pain, swelling. 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 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; and (9) 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°, 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).

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

Materials

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

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 Southern Implants (*or Cochlear Vistafix 2 – refer to section* ***Interchangeability with Cochlear Vistafix 2 components*** *later in this document*) 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.

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.

MR conditional

Non-clinical testing has demonstrated that the Southern Implants dental implants, metallic abutments and prosthetic screws are MR conditional. A patient with these devices can be safely scanned in a MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only.
- Maximum spatial gradient magnetic field of 4000 Gauss/cm (40 T/m).
- Maximum MR system reported, head specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) or whole body averaged specific absorption rate (wbSAR) of 1 W/kg.

Under the scan conditions defined above, the Southern Implants dental implants, abutments and prosthetic screws are expected to produce

a maximum temperature rise of 5.8°C after 15 minutes of continuous scanning. In the non-clinical testing, the image artifact caused by the device extends approximately 20 mm from the Southern Implants dental implants, abutments and prosthetic screws, when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system. Removable restorations should be taken out prior to scanning, as is done for watches, jewellery etc. Should there be no MR symbol on the product label, please note that this device has not been evaluated for safety and compatibility in the MR environment. This device has not been tested for heating or migration in the MR environment.

Interchangeability with Cochlear Vistafix 2 components

The Southern Implants IE3, IE4 and IE6 implants and abutments may be used with the Cochlear Vistafix 2 range. Corresponding components are presented in the table below.

Table E: Interchangeable Southern Implants / Vistafix 2 components

Description	Southern Implants product code	Vistafix 2 product code
Implant length 3mm	IE3	90438
Implant length 4mm	IE4	90440
Cover screw	SC4	90620
Abutments		
Implant-level healing abutment	TBE8n	90436
Abutment-level healing abutment	HB-4	
	HB-6	
Standard abutment (various lengths)	ABE-SET	90780
Gold cylinder for standard abutment	GCP3	90772
Temporary cylinder for standard abutment	TC9	
Console abutment	No Southern Implants variant available	90426
		90427
		90428
		90429
Impression coping	CB1	90379
		90377
Laboratory analogues		
Abutment replica	LS1	90374
Implant replica	LS12	
Retaining screws		
1 Series, Titanium, Slotted	TSS1	90338
1 Series, Gold, Hex	GSH1	
1 Series, Titanium, Hex	TSH1	
1 Series, Gold, Unigrip	GSU1	
1 Series, Titanium, Unigrip	TSU1	
1 Series, Brass, Hex (laboratory)	BSH1	

Basic UDI

Product	Basic-UDI Number
Basic-UDI for General Dental Implants	600954403869

Related literature and catalogues

CAT-2010 - Osseointegrated Fixtures 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 — Rx ONLY Prescription device* — STERILE R Sterilization using Irradiation — 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 — EC REP Authorize Representative in the European Community — REF Catalog number — Date of Manufacture — Single sterile barrier system with protective packaging inside

* 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.