SOUTHERNIMPLANTS®
Innovative Treatment Solutions

South Africa - Headquarters: 1 Albert Road, Irene, 0062, RSA
T: +27-12-667-1046 | **E:** info@southernimplants.com

EC REP
Southern Implants Europe AB: Holmgatan 30, S-791 71 Falun, Sweden
T: +46 23 13300 | **E:** ecrep@southernimplants.com

Subsidiaries

Australia
Southern Implants Australia
T: +61-(0)-8-9466-2627
E: info@southernimplants.com.au

Spain and Portugal
Southern Implants Iberica
T: +34 935 053 507
E: info@southernimplants.es

United Kingdom and Ireland
Southern Implants UK
T: +44-20-8899-6845 / 6 / 7
E: info@southernimplants.co.uk

USA and Canada
Southern Implants North America Inc.
T: +1-561-472-0990
E: customercare@southernimplants.com

Intended use
Southern Implants® dental abutments are intended to be used in the Maxilla or Mandible for supporting a prosthesis on endosseous implants in order to restore chewing function for the patient. This device is a medical device. The overdenture abutments are intended for single use on a single patient.

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

Intended environment
This device is intended to be used in a dental laboratory for making of the restoration, and in a clinical environment such as an operating theatre or a dentist consultation room for final clinical procedures.

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
Overdenture Abutments are premanufactured abutments that is connected directly to an endosseous implant and is used in multiple unit reconstructions to retain a tissue-supported overdenture in patients with extensive bone or soft tissue loss. These components are supplied non-sterile.

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,
- immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge,
- 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.

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.

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 or aspired 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.

Compatibility information
SI Implants should be restored with Southern components. In the SI range there are 5 implant connections, the implant code and connection type, can be identified by specific abbreviations in the product codes. Range ‘identifiers are summarized in table A.

Table 1

Implant Connection type	Compatible prosthetic device
External hex (EX)	Parts labelled EQ-IP- (*), EQ-IBN- (*), EQ-IB- (*)
TRI-NEX® (EL) (Lobe)	Parts labelled Z-EQ-131TN35(*), Z-EQ-131TN43(*), Z-EQ-131TN5(*)
Deep Conical (DC)	Parts labelled EQ-DC(ø)-(L)
Internal Hex (M)	Parts labelled EQ-M-(*) (used with ø3.75,4.2 & 5.0mm platforms)
Internal Hex Provata® (M) (Z)	Parts labelled EQ-M-(*) (used with ø4.0, 5.0, 6.0mm platforms)
IT (ITS) Octagon	Parts labelled Z-EQ-131IT48(*) (used with ø4,8mm platforms)

(*) is indicative of various lengths available.

NOTE: TRI-NEX® (Lobe) and IT (Octagon) implant equator abutments are supplied with a smart box housing and retention caps. For External Hex, Internal Hex (M-Series & Provata®) and DC (Deep Conical) ranges the housing and retentive caps needs to be ordered separately.

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.
Re-using 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

Cleaning and disinfection
An implant restoration is a removable denture attached to a Southern Implants overdenture abutment. Before intraoral use the final restoration

needs to be cleaned and disinfected, as per restorative material manufacturer's instructions.

Sterilization

Southern Implants recommends the following procedure to sterilise the restoration prior to use:
Methods to sterilize the restoration and abutment screw

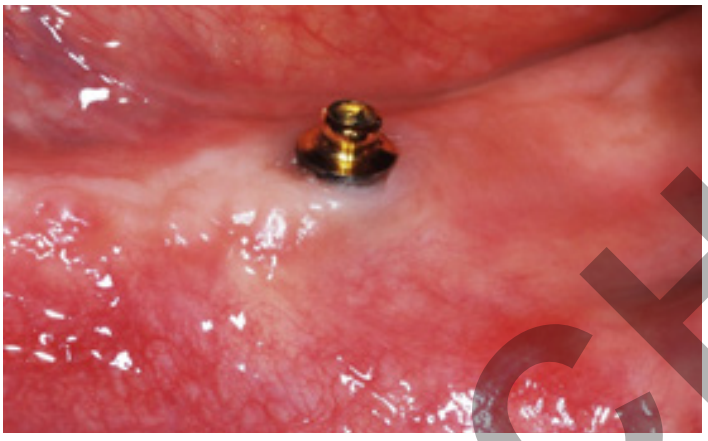
1. Pre-vacuum sterilization method: Steam sterilise the abutments at 132°C (270°F) at 180-220kPa for 4minutes. Dry for at least 20 minutes in the chamber. Only an approved wrap or pouch for steam sterilization must be used.
2. Pre-vacuum sterilization method: Wrapped, steam sterilize at 135°C (275°F) for 3minutes. Dry for 20 minutes in the chamber. Use a wrap or pouch that is cleared for the indicated steam sterilization cycle.

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

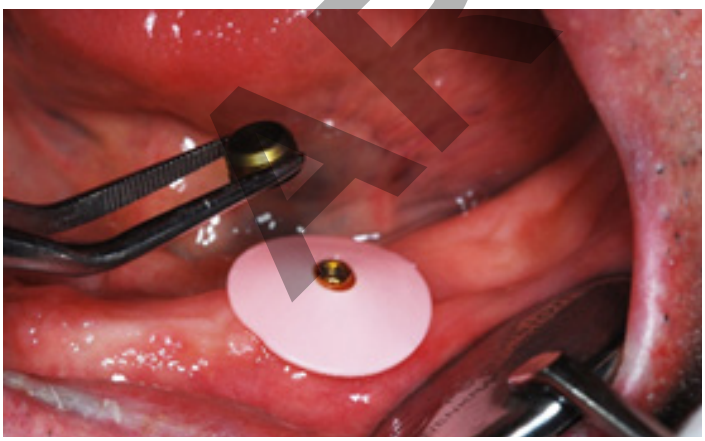
Surgical procedure

Chairside

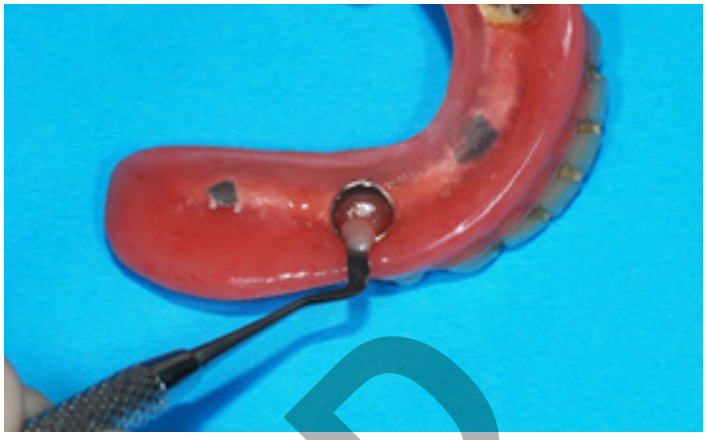
1. Select the OT Equator with the appropriate cuff height. Screw the OT Equator into the implant.



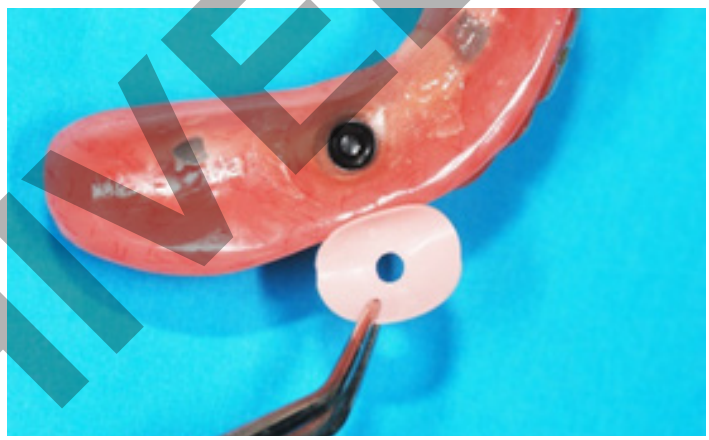
2. Place the protective disk over the OT Equator. Then, place the stainless-steel housing with cap on the attachment.



3. Fill the space corresponding to the housings with self curing resin. Insert the prosthesis into the final position.

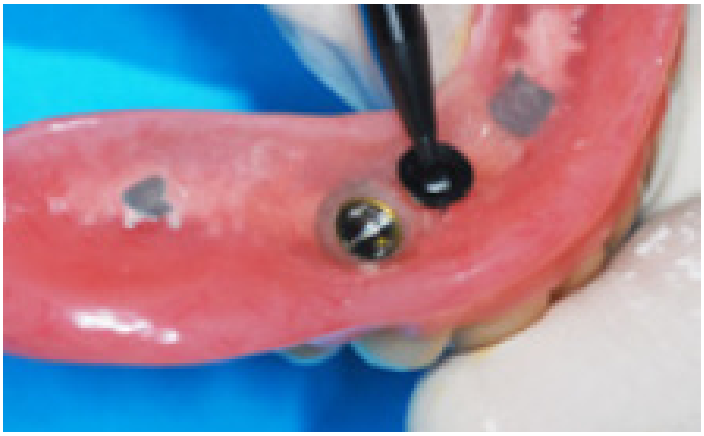


4. Once the resin has cured, remove the protective disk.

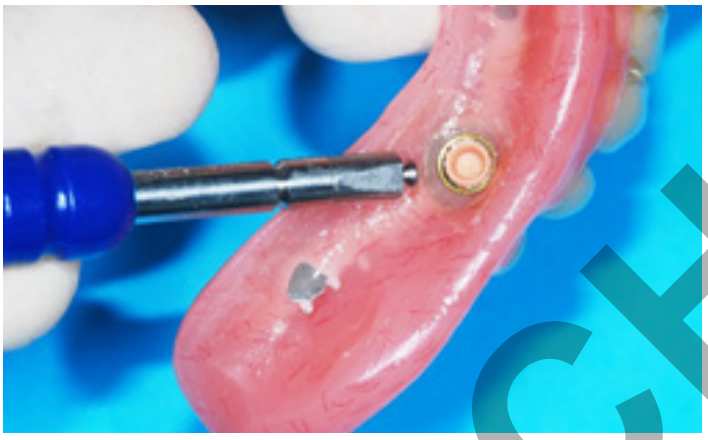


5. Remove excess resin with bur and polish for passive connection.

6. Remove black protector cap with cap extractor tool.

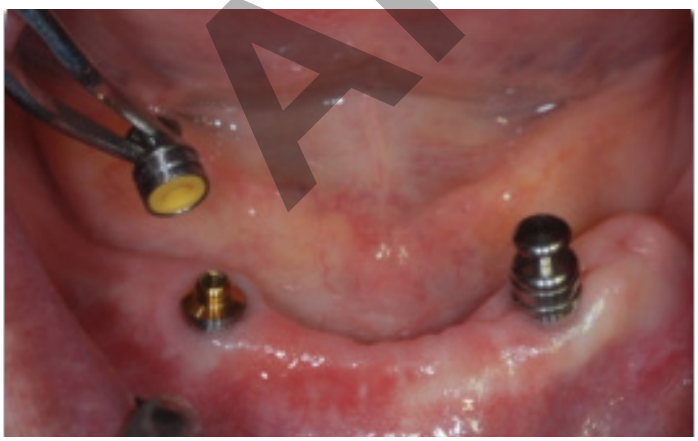


7. Using the cap insertion tool, select 1 of 4 Ot Equator female caps for desired retention.

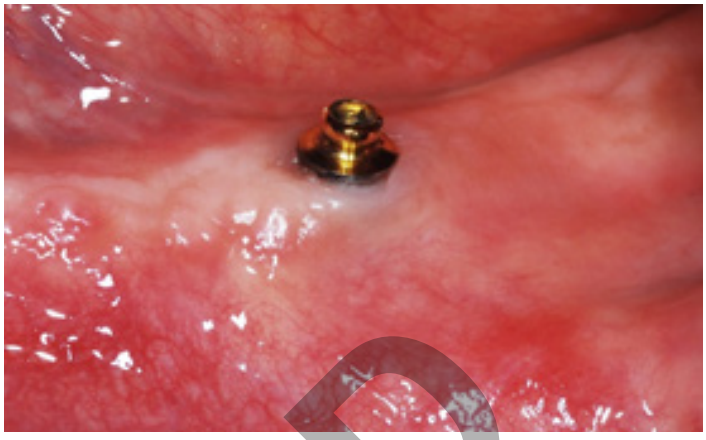


Laboratory procedure, for analogue technique

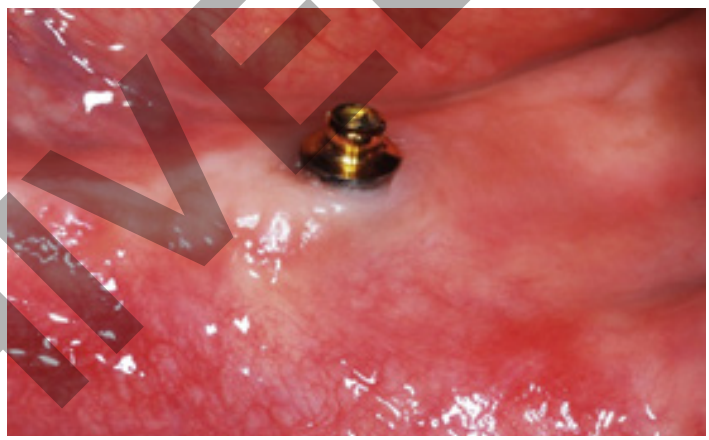
1. Place the Pick-up impression coping onto the equator abutment, take the impression.



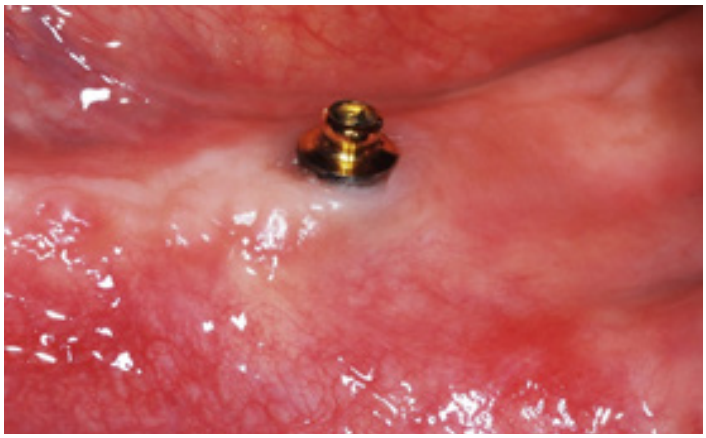
2. Place the laboratory analogues into the impression copings and pour the laboratory model.



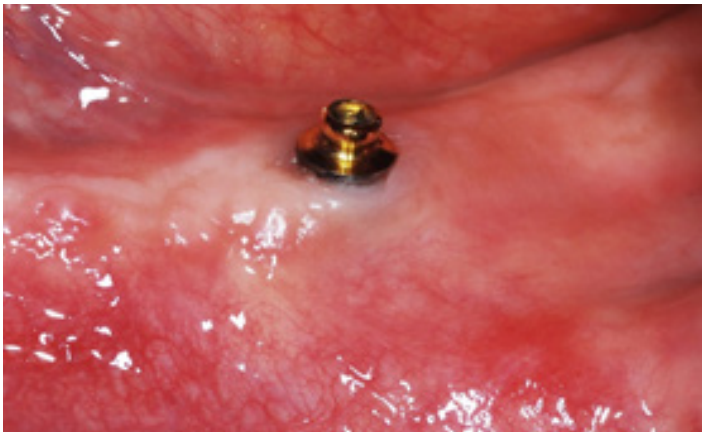
3. Proceed with waxing, teeth set-up of the denture and try-ins.



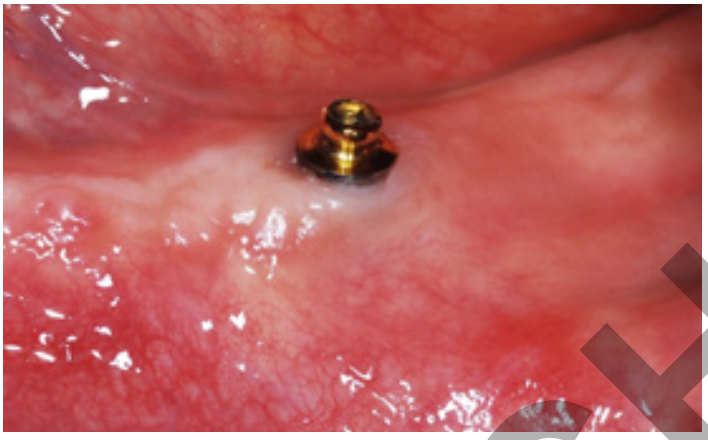
4. Before curing the resin, connect the retentive housing with the Black positioning cap on the equator lab analogue.



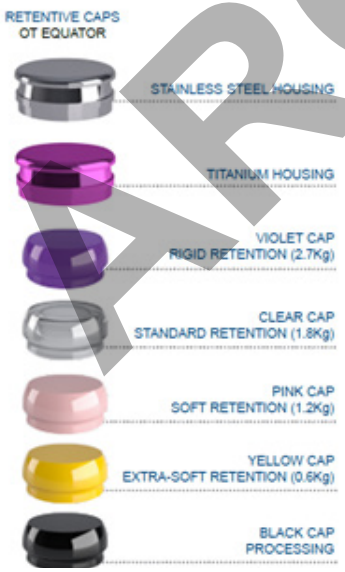
5. After curing remove the Black positioning cap from the metal housing with the cap extractor tool. Insert the retentive cap of choice



6. Return to the dentist office.



Retentive cap information



Torque values and driver information

Table 2

Implant diameter	Torque	Driver
External hex		
ø3.0mm	20Ncm	I-QDI-S/M/L, I-HQD-S/M/L, I-WI-QS/M/L
ø3.25, 4.0mm	20-25Ncm	
Trinex®		
ø3.5mm	20-25Ncm	Z-I-EQ25
ø 4:3, 5.0mm	25-25Ncm	
DC		
ø3.0mm	5-10Ncm	I-QDI-S/M/L, I-HQD-S/M/L, I-WI-QS/M/L
ø3.5, 4.0mm	20Ncm	
ø5.0mm	20-25Ncm	
Internal Hex (M-Series & Provata®)		
ø3.75, 4.2, 5.0mm M series	20-25Ncm	I-QDI-S/M/L, I-HQD-S/M/L, I-WI-QS/M/L
ø4.0, 5.0, 6.0mm Provata Implant:	20-25Ncm	
IT Octagon		
ø4.8mm platform IT Implant,	20-25Ncm	Z-I-EQ25

Clinical benefits

Patients can expect to have their missing teeth replaced and/ or crowns restored. Screwdrivers are used in dental procedures or in dental implant crowns & bridges.

Healing

The healing time required for osseointegration depends on the individual and treatment protocol.

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. 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.

Materials

Overdenture abutments: Commercially Pure Titanium (Grade 4 or 5)

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.

MR Safey

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

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

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).

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 Metal Abutments	600954403872

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 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 — NON STERILE Non-sterile — Caution — Consult instruction for use — Use by date (mm-yy) — Do not reuse — Do not re-sterilize — LOT Batch code — Do not use if package is damaged — MD Medical Device

* Prescription device: Rx only. Caution: Federal Law restricts this device to sale by or on the order of a licenced physician or dentist.

Canada licence exemption: Please note that not all products may have been licensed in accordance with Canadian law.