English

INSTRUCTIONS FOR USE: Southern Implants® Osseointegrated Fixtures

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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 implant labels are colour coded according to the diameter of the implants.

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.

Indications for use

Southern Implants Osseointegrated Fixtures is indicated for the attachment of an external aesthetic restoration prosthesis for the restoration of a physical defect when other means of attachment are inadequate. The endosseous implant provides the bone anchorage for the prosthetic attachment. These devices are indicated for use in the maxillo-craniofacial region (including ear, nose and eye).

Contraindications

Do not use in:

- patients allergic or hypersensitive to titanium
- cases where the remaining bone is too diminished to allow implant installation
- cases where there is insufficient blood supply to the implant site
- patients with insufficient mental health precluding patient cooperation
- patients who abuse drugs or alcohol
- cases where a pre-operative screening exposes possible risks to the healing of the bone or soft-tissue
- patients who by nature of their condition, occupation or activity will be unable to keep the implant site clean

Warnings

Southern Implants Osseointegrated Fixtures have only been validated for use with the corresponding Southern Implants abutments and accessories. Although care has been taken to create interfaces that are equivalent to similar products on the market, Southern Implants cannot guarantee outcomes obtained using components from other manufacturers. Please refer to the product catalogue for interface requirements. Southern Implants will not accept liability for damage caused by improper selection of incompatible abutments and accessories.

All Southern Implants' products are intended to be used by appropriately trained and licensed professionals. For the safe and effective use of Osseointegrated Fixtures, it is strongly suggested that specialised training be undertaken, including hands-on training to learn proper technique and radiographic evaluations. **THESE INSTRUCTIONS ARE NOT INTENDED AS A SUBSTITUTE FOR ADEQUATE TRAINING**. 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 damage to anatomical structures during placement, implant failure and/or loss of supporting bone. Southern Implants will not accept liability for damage caused by improper implant treatment.

Do not reuse Implants, Cover screws, Temporary Abutments and Abutments. These are single-use products. Re-using these components may result in damage on the surface or critical dimensions. This may result in performance and compatibility issues. The removal of proteins from the metal (such as titanium) is extremely difficult and reuse can lead to secondary infections.

Electro-surgery should not be attempted around metal implants, as they are conductive.

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 prosthetic. The implants should emerge in a place where the attachment can be concealed within the bulk of the prosthetic, and should not make it difficult for the patient to detach.

One-stage vs two-stage surgery, healing periods and irradiation

The surgeon can decide to follow a two-stage or one-stage procedure based on various clinical factors. Healing timeframes are based on the same clinical considerations. Therefore, the following table provides our recommendations for healing periods and the choice between one-stage and two-stage procedures.

As a precaution, implant sites that have been irradiated should follow a two-stage procedure, and thus a 4 – 6 month healing period.

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: < 3 mm bone thickness for any implant
Healthy soft-tissue/hard-tissue	Orbital, nasal and other craniofacial defects
	Compromised or soft bone
	Irradiated bone
	Compromised soft-tissue condition

SURGICAL AND PROSTHETIC PROCEDURES

Please refer to the accompanying user manual (CAT-1188) for illustrated implant placement and restoration instructions.

POST-PLACEMENT PROCEDURES

Patient homecare

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 non-alcohol wipes can also be used. Tissue health must be reviewed at check-ups.

Treatment schedule

	One-stage	Two-stage
Surgery	-	**First**
Leave to osseointegrate with cover screw	-	3-5 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 implant-abutment 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.

Complications

Soft-tissue complications

If infection occurs, the patient's aftercare routines should be reviewed. An antimicrobial cream can be prescribed if appropriate. The abutment can be removed, if need be, to properly address soft-tissue complications. A new abutment can be placed after the appropriate healing period.

Skin overgrowth

If the skin begins to grow over the abutment, perform skin thickness reduction surgery again. If skin regrowth persists in cases of craniofacial implants, a longer abutment can be fitted.

Implant instability and loss

If the implant loses stability a cover screw can be placed and the skin closed up for osseointegration for another 3-6 months. If there is a failure to osseointegrate, the implant must be removed. In craniofacial sites, a suitable site for a new implant can sometimes be found in adjacent bone. All factors for case selection should be re-evaluated before proceeding with a second implant.

HANDLING, PACKAGING AND LABELING

Storage and handling

Devices should be stored at room temperature. Refer to the individual product packaging label and the corresponding manual for special handling instructions. IMPLANTS MUST NOT BE TOUCHED DIRECTLY. They must be handled and placed by the instruments provided. If an implant is dropped onto the floor, it should not be used.

Packaging

1. Implants: The outer package consists of a rigid, clear box which acts as protection for the inner package. The inner package consists of a clear plastic-formed bubble-type base with a “peel-back” lid. The contents of this inner package are sterile. Labelling information is located on the surface of the peel-back lid and on the outside of the rigid box. Within the inner package there is a hollow tube which contains one implant and one cover screw. Sterility is assured unless the container or seal is damaged or opened.
2. Other sterile components are packed in a peel pouch and sterilised by gamma irradiation. Labelling information is located on the bottom half of the pouch inside the packet. Sterility is assured unless the pouch is damaged or opened.
3. Other non-sterile components used in the laboratory are supplied clean but not sterile. Labelling information is located on the bottom half of the pouch inside the packet.

Cleaning and Sterilization

All implants and some abutments are shipped sterile 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. DO NOT re-sterilize or autoclave these components. Products provided non-sterile must be cleaned and sterilized according to the directions in the Cleaning & Sterilization Guidelines Manual (CAT-3108) prior to use.

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

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

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.

MR safety

Nonclinical 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 3000 Gauss/cm (30 T/m).
- maximum MR system reported SAR corresponding to Normal Operating mode for all landmarks (Head SAR of 3.2 W/kg for head landmark, 2 W/kg whole body, and appropriate partial body SAR for other landmarks). For imaging landmarks above the thorax, a continuous scan time of 15 minutes will require a cooling delay of at least 5 minutes.
- 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.

Summary of Safety and Clinical Performance (SSCP)

As required by the European Medical Device Regulation (MDR; EU2017/745), a Summary of Safety and Clinical Performance (SSCP) is available for perusal with regard to Southern Implants® product ranges.

The relevant SSCP can be accessed at https://ec.europa.eu/tools/eudamed.

NOTE: the above website will be available upon the launch of the European Database on Medical Devices (EUDAMED).

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.

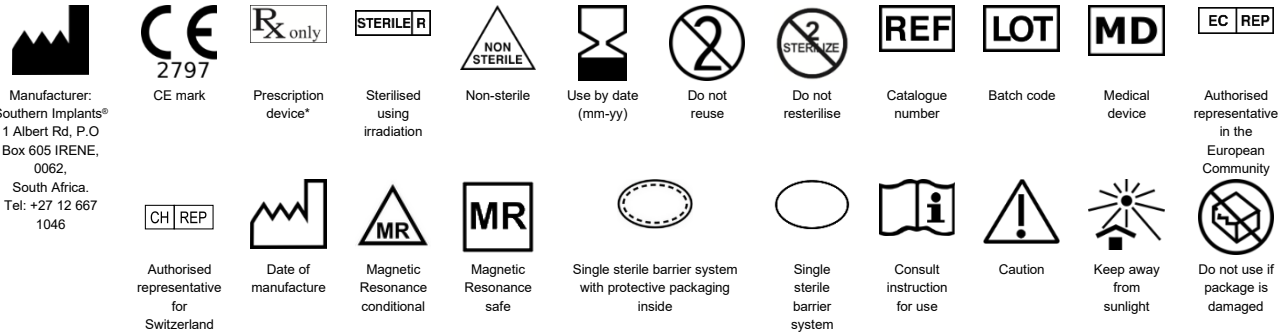
Basic UDI

Product	Basic-UDI Number
Basic-UDI for Osseointegrated Fixtures	60095440422484

Related literature and catalogues

CAT-2010 – Osseointegrated Fixtures Product Catalogue
CAT-1188 – Ultra-short Implant User Manual
CAT-3108 – Cleaning & Sterilization Guidelines Manual

Symbols and warnings



* 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.

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