English

INSTRUCTIONS FOR USE: Southern Implants® Osseointegrated Fixtures

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Description

The Osseointegrated Fixture is a self-tapping tapered implant made of commercially pure Grade 4 Titanium (ASTM F67 and UTS≥900MPa) and feature a smooth (non-threaded) collar. The Osseointegrated Fixtures are available exclusively in fully roughened versions. This is achieved by grit-blasting the body of the implant with aluminium oxide to provide a surface roughness of 1-2µm.

Intended use

The Osseointegrated Fixtures are intended for surgical placement in the skull, mainly the mastoid process, periorbital and perinasal regions, as a means to provide rigid retention for craniomaxillofacial epistheses.

These devices are intended for single use on a single patient.

Indications for use

The Osseointegrated Fixtures are indicated for use in the restorative treatment of patients with congenital or acquired craniomaxillofacial defects to enable attachment of external aesthetic restorations or epistheses in cases where autologous reconstruction is deemed unsuitable, the outcome of autologous reconstruction is regarded as insufficient or other means of attachment are considered to be inadequate.

Intended user

The intended user for the Osseointegrated Fixtures includes maxillofacial surgeons, plastic surgeons, anaplastologists (as part of the surgical planning and epistheses design) and other appropriately trained medical professionals.

Intended environment

This system is intended to be used in a sterile, clinical environment such as an operating theatre.

Intended patient population

The intended patient population for the Osseointegrated Fixtures includes those with acquired or congenital defects of the craniofacial or maxillofacial region that are eligible, or otherwise not contraindicated, for an extra-oral implant-retained episthesis.

In the context of paediatric patient populations, care should be taken to ensure that the bone is adequately developed and has sufficient quantity and thickness to support the placement of the implants.

Compatibility information

Southern Implants' implants should be restored with compatible Southern Implants Prosthetic Components. Use components that correspond to the connection type and prosthetic platform when restoring the Osseointegrated Fixtures. For further information see the Osseointegrated Fixtures Product Catalogue (CAT-2010) and Instructions for Use (CAT-8084-HC and CAT-8085-HC).

Table A – Osseointegrated Fixtures One-Stage surgery and Two-Stage Surgery

<table>
<tr><th>Item code</th><th>Implant Diameter x Length (mm)</th><th>One-stage surgery Abutments</th><th colspan="2">Two-stage surgery Abutments</th></tr>
<tr><td>IE3*</td><td>Ø3.75 x 3</td><td rowspan="5">TBE8n
(healing abutment)

OR

ABEx (standard abutment)
in combination with
HBx (temporary healing cap)</td><td rowspan="5">SC4
(healing abutment)</td><td rowspan="5">TBE8n
(healing abutment)

OR

ABEx (standard abutment)
in combination with
HBx (temporary healing cap)</td></tr>
<tr><td>IE4*</td><td>Ø3.75 x 4</td></tr>
<tr><td>IE6*</td><td>Ø3.75 x 6</td></tr>
<tr><td>IET4</td><td>Ø4.50 x 4</td></tr>
<tr><td>IETi4</td><td>Ø4.50 x 4</td></tr>
</table>

Table B – Osseointegrated Fixtures Drivers

Item code	Compatible Driver
Implants	
IE3*	I-CON-X/XS, I-CONU-X/XS
IE4*	
IE6*	
IET4	
IETi4	I-HID-S/M/L, I-HIDU-S/M/L
Abutments	
SC4	I-CS-HD, I-HHD-09, I-WI-09
TBE8n	I-HD-S/M/L, I-HHD-22S/M/L, I-WI-22S/M/L
ABEx	I-AD, I-HAD, I-WI-A
Prosthetic Components for Standard Abutments	
HBx	I-HD-S/M/L, I-HHD-22S/M/L, I-WI-22S/M/L
TC9 and TSH1	
GCP3 and TSH1	

**Osseointegrated Fixtures IE Implants are packed with their corresponding cover screw*
x denotes the various collar heights available for the components

Clinical performance

The Osseointegrated Fixtures are intended to provide a rigid retention method for a removable aesthetic prosthesis in the restorative treatment of craniomaxillofacial defects. The rigid and secure retention of the prosthetic restoration is accomplished through the stability of the implant itself. This stability is achieved through the fixture's surgical implantation into the bone and subsequent successful osseointegration. Consequently, the clinical performance of the Osseointegrated Fixtures is primarily defined by the degree of osseointegration achieved.

Clinical benefits

The clinical benefits associated with the prosthetic restoration of craniomaxillofacial defects are significant, as this treatment can greatly enhance the functional and aesthetic outcomes of the patient. These benefits include the successful restoration of the defect and the improvement of the patient's facial aesthetics. Therefore, the clinical benefit of the Osseointegrated Fixtures encompasses the restoration of the defect, the retention of the prothesis and the patient's satisfaction with the aesthetic result. Furthermore, since this treatment addresses the emotional and psychological impact of facial deformities, it is anticipated that a successfully restored patient will experience an improvement in social functioning, an enhanced overall psychosocial well-being and a higher level of self-esteem and self-confidence.

Storage, cleaning and sterilisation

The component is 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®. The devices must be stored in a dry place at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics. Do not reuse components indicated for single-use only. Reusing these components may result in:

- damage to 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 single-use components.

Contraindications

Contraindications are circumstances, conditions, symptoms or factors that increase the risks associated with a medical procedure, drug or treatment. A contraindication is one that results in the progression of treatment to be inadvisable without exception.

The contraindications of all device groups used as part of the specific treatment or procedure apply. Therefore, the contraindications of the systems/medical devices utilised as part of implant surgery/therapy should be noted and the relevant documents consulted.

The contraindications for Osseointegrated Fixtures include:

- cases where full functional support for the episthesis is not attainable (i.e., the number of implants that could be placed would provide insufficient support even if combined with other retention methods)
- cases where the remaining/available bone is too diminished to allow implant installation
- a lack of oncological radicality (i.e., persistent cancer presence or high risk of cancer recurrence due to potentially incomplete eradication)
- conditions that prevent proper implant hygiene and/or patient cooperation including, but not limited to, severe mental disorders (e.g., dementia), cachexia, drug or alcohol addiction or disability
- cases where the patients, by nature of their occupation or activity, will be unable to keep the implant site clean
- cases where there is an inability to adhere to a follow-up schedule
- patients with coexisting major systemic disease or who are otherwise medically unfit for implant surgery
- patients with titanium allergies or hypersensitivities
- presence of infection or pathology at the implant site

Warnings and precautions

THESE INSTRUCTIONS ARE NOT INTENDED AS A SUBSTITUTE FOR ADEQUATE TRAINING.

- For the safe and effective use of the Osseointegrated Fixtures it is strongly suggested that specialised training be undertaken. This training should include hands-on methods to gain competency on the proper technique, biomechanical requirements and radiographic evaluations required for the specific system.
- Improper technique can result in an increased potential for implant failure, damage to nerves/vessels, loss of supporting bone or other more severe complications and side effects.
- Use of the device with incompatible or non-corresponding devices can result in device failure or poor performance.
- The use of non-sterile items can lead to secondary infections of the tissue or transfer infectious diseases.
- Failure to perform appropriate cleaning, re-sterilisation and storage procedures as per the Instructions for Use document can result in device damage or secondary infection.
- Blunt drills may cause damage to the bone which could compromise osseointegration.

It should be noted that training should be undertaken by *both* new and experienced implant users before using a new system or attempting a new treatment method.

It is important that thorough screening of prospective implant candidates be performed. This screening should include, at minimum, a comprehensive medical history taking in which special consideration is given to the aetiology of the defect and a visual/radiological inspection to determine the condition of the bone, bone dimensions and anatomical landmarks. Failure to accurately estimate lengths of drills relative to radiographic measurements can result in permanent injury to nerves or other vital structures.

Patient co-operation is a critical factor in the success of an extraoral implant and its importance should be thoroughly communicated to the patient during the initial screening process and all subsequent appointments. This co-operation includes the adherence to routine follow-ups and home care procedures throughout its lifecycle in order to maintain excellent hygiene around the implant site.

Once the patient has been screened and considered suitable for an implant-retained prosthesis, it is vital to ensure proper preoperative planning is performed. This preoperative planning should include craniofacial MRI and CT scan analysis, 3D reconstructions of the craniofacial bones, and clinical examination of the deformity. Pre-establishment of implant sites is crucial, during which consideration is given to bone parameters (thickness and shape), implant stability, minimization of the impact of unwanted forces on the implants, planning locations for replacement implants in case of

implant failure at the originally selected sites, and maintaining the angles at which the implants are inserted so that other prosthetic components can subsequently be fixed to them.

Furthermore, this preoperative planning should include consultation between a multi-disciplinary team, including a prosthetist or anaplastologist. These factors are essential to ensure the most optimal location is selected for implant placement to maximise implant stability in the bone and promote a well-fitting prosthesis and are important considerations in the promotion of successful treatment outcomes.

For successful implant treatment, it is important to (1) minimise the trauma to the host tissue as this increases the potential for successful osseointegration, (2) identify actual measurements relative to the radiographic data as failing to do so could lead to complications, and (3) be aware and avoid damage to vital anatomical structures such as nerves, veins and arteries. Injury to these structures may cause serious complications, including injury to the eye, nerve damage and excessive bleeding.

It should be noted that the prognosis of the implant is dependent on implant site where the temporal region generally presents with better prognosis of survival and fewer complications and the orbital areas generally presents with a greater risk.

Special care should be taken when treating patients with local or systemic risk factors that could affect the healing of the bone and soft tissue or otherwise increase the severity of the side effects, risk of complications and/or implant failure.

These factors represent high risk patients and include:

- patients that present with mild psychiatric disorders
- patients that present with pre-existing neurologic dysfunction
- patients that present with poor craniofacial bone condition (inadequate bone quality and/or quantity)
- patients that present with compromised vasculature on the surgical bed
- patients that present with decreased soft tissue or bone healing potential due to local or systemic conditions, history of trauma or infection in the region etc.
- patients that present with a presence of extensive soft tissue scarring
- patients with a history of orofacial radiation therapy following ablative oncologic surgery
- patients with conditions or in circumstances that may interfere with adequate hygiene maintenance e.g., minors (parent/guardian to ensure adequate cleaning)
- patients that present with a lack of sufficient tissue covering
- patients with a history of smoking/vaping/tobacco use
- patients on chronic medications that may delay healing, increase the risk of complications or promote the development of osteoradionecrosis including, but not limited to, chronic steroid therapy, anti-coagulant therapy, TNF-α blockers, bisphosphonate and cyclosporin
- patients that present with pathological skin conditions in the region of the defect (e.g., psoriasis)

The age of the patient should also be considered as age-associated natural decline in vascularity, healing capacity and bone density/quality can affect the ability of the bone to fuse with the implant. However, factors such as overall bone health and the specific condition of the patient’s bones will play a significant role.

Bacterial and/or recurrent meningitis is an increased risk in patients with cranio-facial anatomical abnormalities, therefore, this increased risk should be considered during the planning phase of any surgery or treatment modality provided to these patients where extra precautionary measures should be taken.

With the combination of the thorough screening of prospective implant candidates, a user with a high level of competence in the use of the system and strict adherence to aftercare instructions and hygiene maintenance measures, the potential for complications and severe side effects can be reduced.

The responsibility for proper patient selection, adequate training and experience in implant placement and the provision of the appropriate information required for informed consent rests with the practitioner.

Should the device not operate as intended, it must be reported to the manufacturer of the device. The contact information or the manufacturer of this device to report a change in performance is: sicomplaints@southernimplants.com.

Side effects

The side effects associated with the implantation of the Osseointegrated Fixtures are comparable with the side effects associated with other forms of craniofacial surgery.

These include:

- Pain or tenderness
- Localized inflammation
- Soft tissue irritation
- Discomfort
- Hematoma or bruising
- Bleeding

Additionally, the normal side effects associated with anaesthesia should also be expected.

In addition to the side effects expected as a result of the implantation of the Osseointegrated Fixtures, there are also additional potential or foreseeable complications. These complications represent the relative risks associated with proceeding with the treatment of these patients where further intervention, medical treatment or removal of the implant may be required.

These include:

- Abutment and/or suprastructure loading
- Allergic reaction to implant material
- Anatomical landmark damage
- Frontal sinus infection
- Implant contact with underlying sigmoid sinus or dura when inserted in the mastoid region
- Implant fracture/failure
- Implant instability
- Infection of the surrounding soft tissue
- Intraoperative dural exposure
- Intraoperative venous injury/bleeding
- Mastoid air cell breach
- Nerve injury or dysfunction resulting in transient or permanent weakness, numbness, or pain
- Perforation of the dura
- Prosthetic compromise due to improper implant placement
- Prosthetic failure
- Skin irritation under the prosthesis
- Skin overgrowth around/over abutment
- Soft tissue complications including erythema, moisture secretion and granulation
- Wound dehiscence or improper healing

Precaution: maintaining sterility protocol

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.

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.

Magnetic Resonance (MR) Safety

Nonclinical testing has demonstrated that the Southern Implants® 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 2 W/kg for head landmark, 1 W/kg whole body (for landmarks within 30 cm of the implant) or 2 W/kg whole body (for landmarks more than 30 cm from the implant), and appropriate partial body SAR for other landmarks). For imaging landmarks above the thorax, 15 min of scanning at normal operating mode for landmarks greater than 30 cm from the implant with a whole body SAR of 1W/kg for imaging landmarks within 30 cm of the implant.
- 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.

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.

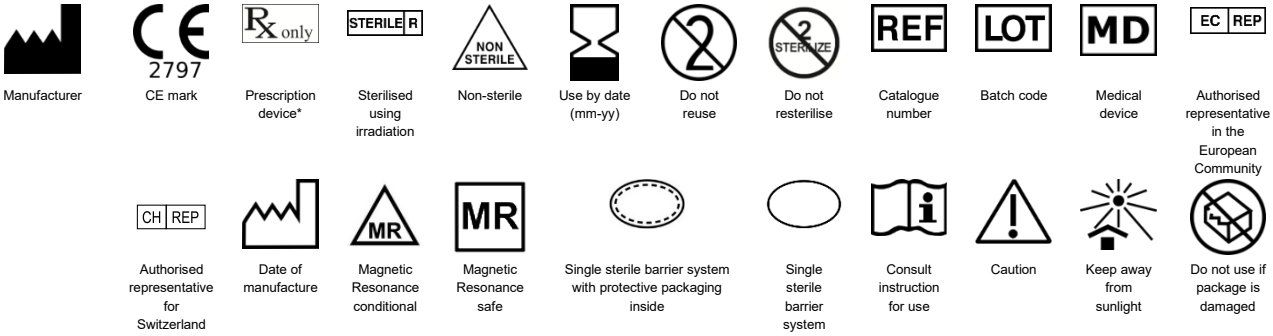
Basic UDI

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

Related literature and catalogues

CAT-2010 – Osseointegrated Fixtures Product Catalogue
CAT-8084-HC – Osseointegrated Fixtures Abutments Instructions for Use
CAT-8085-HC – Osseointegrated Fixtures Drills and Handpiece Devices Instructions for Use

Symbols and warnings



Manufacturer | CE mark | Prescription device* | Sterilised using irradiation | Non-sterile | Use by date (mm-yy) | Do not reuse | Do not resterilise | Catalogue number | Batch code | Medical device | Authorised representative in the European Community

Authorised representative for Switzerland | Date of manufacture | Magnetic Resonance conditional | Magnetic Resonance safe | Single sterile barrier system with protective packaging inside | Single sterile barrier system | Consult instruction for use | Caution | Keep away from sunlight | Do not use if package is damaged

* 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.