English

INSTRUCTIONS FOR USE: Southern Implants® Internal Octagon Implants

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Description

The Internal Octagon (IT) implants are tissue level implants that feature internal Morse Taper prosthetic interfaces being available with either a tapered or parallel walled body shape.

The Internal Octagon implant is also available in the angulated platform Co-Axis® design, with a built-in platform angulation of 12°, this design enables tilting of the implant without compromising the restorative emergence angle. Implants packed with a fixture mount are also supplied with a cover screw in the base of the packaging tube.

Intended use

Southern Implants® Dental Implants are intended to be surgically placed in the upper or lower jaw to provide a support structure and point of attachment for prosthetic devices.

Indications for use

The Internal Octagon (IT) Implant System is intended to be implanted in the upper or lower jaw arches to provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or full arch prostheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.

Compatibility information

Southern Implants' implants should be restored with Southern Implants' components. Use components that correspond to the connection type and prosthetic platform when restoring the Internal Octagon (IT) implants. For further information see the Internal Octagon (IT) Implants Product Catalogue (CAT-2005).

Table A – Internal Octagon (IT) implant range

Implant Diameter (mm)	Item Code	Implant Length Codes	Implant Lengths (mm)	Cylindrical or Tapered (C / T)
Ø3.3	ITC3	06 / 08 / 10 / 12 / 14	6 / 8 / 10 / 12 / 14	C
		06f / 08f / 10f / 12f / 14f	6 / 8 / 10 / 12 / 14	C
Ø4.0	ITT4	08 / 10 / 12 / 14	8 / 10 / 12 / 14	T
		08f / 10f / 12f / 14f	8 / 10 / 12 / 14	T
Ø4.1	ITC4	06 / 08 / 10 / 12 / 14	6 / 8 / 10 / 12 / 14	C
		06f / 08f / 10f / 12f / 14f	6 / 8 / 10 / 12 / 14	C
Ø4.9	ITC5	06 / 08 / 10 / 12 / 14	6 / 8 / 10 / 12 / 14	C
		06f / 08f / 10f / 12f / 14f	6 / 8 / 10 / 12 / 14	C
Ø4.9*	ITC6-5	06 / 08 / 10 / 12	6 / 8 / 10 / 12	C
		06f / 08f / 10f / 12f	6 / 8 / 10 / 12	C
Ø5.0	ITT5	08 / 10 / 12 / 14	8 / 10 / 12 / 14	T
		08f / 10f / 12f / 14f	8 / 10 / 12 / 14	T
Ø5.0*	ITT6-5	08 / 10 / 12	8 / 10 / 12	T
		08f / 10f / 12f	8 / 10 / 12	T
Ø6.0*	ITT6	08 / 10 / 12	8 / 10 / 12	T
		08f / 10f / 12f	8 / 10 / 12	T

* Wide interface

Implants with "f" at end of code indicates that the implant is packed with fixture mount and cover screw

Implant Diameter (mm)	Item Code	Implant Length Codes (**)	Implant Lengths (mm)	Cylindrical or Tapered (C / T)
Ø4.0	ITST12d-4(**)f	08 / 10 / 12 / 14	8 / 10 / 12 / 14	T
Ø5.0	ITST12d-5(**)f	08 / 10 / 12 / 14	8 / 10 / 12 / 14	T

Prosthetic platform angled at 12°, supplied with fixture mount

Storage, cleaning and sterilisation

The component is supplied sterile (sterilised by gamma irradiation) and is 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

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

The contraindications specific to this device group include:

- patients medically unfit for oral surgical procedures,
- cases where an adequate number of implants cannot be placed to provide full functional support of the prosthesis,
- patients with inadequate bone quality/quantity,
- patients with uncontrolled bleeding disorders,
- presence of infection at the implant site,
- patients with severe vascular impairment,
- patients with uncontrolled endocrine disorders,
- patients undergoing high does steroid therapy,
- patients with metabolic bone disease,
- patients with incomplete mandibular or maxillary growth,
- patients with a weakened immune system or inadequate wound healing capacity,
- patients with allergies or hypersensitivity to the material used (titanium).

Warnings and precautions

IMPORTANT NOTICE: THESE INSTRUCTIONS ARE NOT INTENDED AS A SUBSTITUTE FOR ADEQUATE TRAINING

- To ensure the safe and effective use of dental implants, new technologies/systems and the Metal Abutment devices, it is strongly recommended that specialised training be undertaken. This training should include hands-on methods to gain competency on the proper technique, the system's biomechanical requirements and radiographic evaluations required for the specific system.
- Improper technique can result in implant failure, damage to nerves/vessels and/or loss of supporting bone.
- Use of the device with incompatible or non-corresponding devices can result in the poor performance or failure of the device.
- When handling devices intraorally, it is imperative that they are adequately secured to prevent aspiration, as aspiration of products may lead to infection or physical injury.
- The use of non-sterile items can lead to secondary infections of the tissue or transfer infectious diseases.
- Failure to adhere to appropriate cleaning, re-sterilization, and storage procedures as outlined in the Instructions for Use can result in device damage, secondary infections, or patient harm.
- Exceeding the number of recommended uses for reusable devices can result in device damage, secondary infection or patient harm.
- The use of blunt drills may cause damage to the bone, potentially compromising osseointegration.

It is crucial to emphasize that training should be undertaken by both new and experienced implant users prior to utilizing a new system or attempting a new treatment method.

Patient Selection and Preoperative Planning
A comprehensive patient selection process and meticulous preoperative planning are essential for successful implant treatment. This process should involve consultation among a multidisciplinary team, including well-trained surgeons, restorative dentists, and laboratory technicians.

Patient screening should include, at a minimum, a thorough medical and dental history, as well as visual and radiological inspections to assess the presence of adequate bone dimensions, the positioning of anatomical landmarks, the presence of unfavourable occlusal conditions, and the periodontal health status of the patient.

For successful implant treatment, it is important to:

1. Minimize trauma to the host tissue, thereby increasing the potential for successful osseointegration.
2. Accurately identify measurements relative to radiographic data, as failure to do so may lead to complications.
3. Be vigilant in avoiding damage to vital anatomical structures, such as nerves, veins, and arteries. Injury to these structures may result in serious complications, including ocular injury, nerve damage, and excessive bleeding.

The responsibility for proper patient selection, adequate training and experience in implant placement, and the provision of appropriate information required for informed consent rests with the practitioner. By combining thorough screening of prospective implant candidates with a practitioner possessing a high level of competence in the use of the system, the potential for complications and severe side effects can be significantly reduced.

High Risk Patients
Special care should be exercised when treating patients with local or systemic risk factors that may adversely affect the healing of bone and soft tissue or otherwise increase the severity of side effects, the risk of complications, and/or the likelihood of implant failure. Such factors include:

- poor oral hygiene
- history of smoking/vaping/tobacco use
- history of periodontal disease
- history of orofacial radiotherapy**
- bruxism and unfavourable jaw relations
- use of chronic medications that may delay healing or increase the risk of complications including, but not limited to, chronic steroid therapy, anti-coagulant therapy, TNF-α blockers, bisphosphonate and cyclosporin

*** The potential for implant failure and other complications increases when implants are placed in irradiated bone, as radiotherapy can lead to progressive fibrosis of blood vessels and soft tissue (i.e., osteoradionecrosis), resulting in diminished healing capacity. Contributing factors to this increased risk include the timing of implant placement in relation to radiation therapy, the proximity of radiation exposure to the implant site, and the radiation dosage at that site.*

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 clinical outcome of treatment is influenced by various factors. The following side effects and residual risks are associated with the device group and may necessitate further treatment, revision surgery or additional visits to the relevant medical professional's office. Furthermore, these side effects and residual risks can occur with varying possible severities and frequencies.

- Allergic reactions(s) to the implant material

- Anaesthesia, paraesthesia, hyperesthesia, and hypoesthesia (transient or permanent)
- Anatomical landmark damage
- Bleeding on probing
- Bruising
- Complications requiring revision surgery
- Damage to adjacent dentition
- Dental injury during surgery
- Hyperplastic soft tissue response
- Implant failure
- Implant fracture
- Improper implant positioning resulting in prosthetic compromise
- Infection (acute and/or chronic)
- Insufficient levels of osseointegration resulting in instability, mobility and/or failure
- Localized inflammation
- Loosening of the abutment screw and/or retaining screw
- Loss or damage to adjacent teeth
- Marginal bone loss
- Micromovements and implant instability
- Misfit or improper connection at the implant-abutment interface
- Overloading of the abutment/implant
- Pain or discomfort
- Peri-implantitis, peri-mucositis or otherwise poor peri-implant soft tissue health
- Periodontal inflammation
- Phonetic difficulties
- Prosthetic failure
- Soft tissue irritation
- Sub-optimal aesthetic result
- Surgical side effects such as pain, inflammation, bruising and mild bleeding
- Wound dehiscence or poor 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)

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

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 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 artefact caused by the device extends approximately 20mm 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.

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 General Dental Implants	6009544038699H

Related literature and catalogues

CAT-2005 – Internal Octagon (IT) Implants Product Catalogue

Symbols and warnings

Manufacturer:
Southern Implants®
1 Albert Rd, P.O
Box 605 IRENE,
0062,
South Africa.
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1046

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

Date of manufacture

Magnetic Resonance

Magnetic Resonance

Single sterile barrier system with protective packaging

Single sterile barrier

Consult instruction

Caution

Keep away from sunlight

Do not use if package is

for conditional safe inside system for use damaged
Switzerland

* 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.