English **INSTRUCTIONS FOR USE: Southern Implants® SI-BASE Abutments**

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Description

SI-BASE Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. SI-BASE Abutments are indicated in Southern Implants' digital workflow: scan files from desktop/intraoral scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories. These abutments are supplied nonsterile and for single use only.

Intended use

SI-BASE Abutments are premanufactured prosthetic components intended to be used for the retention and support of a prosthesis on an endosseous dental implant. Additionally, the abutment can serve as both a digital impression scanning reference and the mounting surface for a restoration using CAD/CAM technology.

Indications for use

SI-BASE Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. The SI-BASE Abutments consist of two major parts. Specifically, the titanium base and mesostructure components make up a multi-piece abutment. The system integrates multiple components of the digital dentistry workflow: Scan files from desktop scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

SI-BASE Abutments are intended for use in all regions of the mouth unless contraindicated by their respective implant's intended use:

- The intended use for the SI-BASE Abutments used with the Ø3.0 External-Hex implants and Ø3.0 Deep Conical implants is limited to replacement of maxillary lateral incisors and mandibular lateral and central incisors.
- The intended use for the SI-BASE Abutments used with the Ø3.3 PROVATA implants and the Ø3.4 External-Hex implants is limited to replacement of maxillary and mandibular lateral and central incisors.

Intended user

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

Intended environment

The intended environment for the Metal Abutments device family is not dissimilar to that of dental implant therapy.

The intended environment of the Metal Abutments system, with respect to dental implant therapy, includes a dental laboratory for the manufacture of the restoration and a clinical environment such as an operating theatre or a dentist consultation room.

Intended patient population

The intended user is not dissimilar to that of dental implant therapy.

The intended patient population for implant therapy is partially or fully edentulous patients requiring prosthetic dental restoration in the upper or lower jaw. Restorations may comprise single teeth, partial or full bridges and are fixed restorations.

Additionally, the intended patient population includes those who have previously received dental implant therapy.

Compatibility information

Southern Implants' implants should be restored with Southern Implants' components. In the Southern Implants' SI-BASE Abutment 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 summarised in Table A.

Table A - Compatible

Implant connection type	Compatible device
External Hex (EX)	Parts labelled SIB-EX-(Ø)-(*) for engaging items
	Parts labelled SIB-NX-(Ø)-(*) for non-engaging items

Tri-Nex (EL) (Lobe)	Parts labelled SIB-EL-(Ø)-(*) for engaging items
Deep Conical (DC)	Parts labelled SIB-DC(Ø)-(*) for engaging items
	Parts labelled SIB-NDC(Ø)-(*) for non-engaging items
Internal Hex (M)	Parts labelled SIB-M-(*) for engaging items (used with Ø3.75, 4.20 and 5.00 mm platforms)
	Parts labelled SIB-NM-(*) for non-engaging items (used with Ø3.75, 4.20 and 5.00 mm platforms)
	Parts labelled SIB-M-PM-(*) for engaging items (used with Ø5.0 mm platform)
Internal Hex PROVATA® (3M/M/Z)	Parts labelled SIB-3M-(*) for engaging items (used with Ø3.3 mm platform)
	Parts labelled SIB-3NM-(*) for non-engaging items (used with Ø3.3 mm platform)
	Parts labelled SIB-M-(*) for engaging items (used with Ø4.0, 5.0 and 6.0 mm platforms)
	Parts labelled SIB-NM-(*) for non-engaging items (used with Ø4.0, 5.0 and 6.0 mm platforms)
	Parts labelled SIB-M-PM-(*) for engaging items (used with Ø5.0 and 6.0 mm platforms)
	Parts labelled SIB-Z-(*) for engaging items (used with Ø6.0, 7.0, 8.0 and 9.0 platforms)
	Parts labelled SIB-NZ-(*) for non-engaging items (used with Ø6.0, 7.0, 8.0 and 9.0 platforms)
	Parts labelled SIB-Z-PM-(*) for engaging items (used with Ø7.0, 8.0 and 9.0 platforms)
Abutment level (MC)	Parts labelled SIB-TMC1 (used with Ø4.8 mm abutment platforms)
	Parts labelled SIB-TMCW1 (used with Ø6.0 mm abutment platforms)

(*) is indicative of various collar heights available

Clinical benefits

Through this procedure patients can expect to have their missing teeth replaced and/or crowns restored.

Storage, cleaning and sterilisation

This component is supplied non-sterile and is indicated for single use. 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. Re-using these components may:

- 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 single-use components.

Southern Implants® recommends one of the following procedures to sterilise the restorations and non-sterile single-use components prior to use:

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

NOTE: users in the USA must ensure that the steriliser, wrap or pouch, and all steriliser accessories are cleared by the FDA, for the intended sterilisation cycle.

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 and sinus pathology.

Warnings and precautions

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

- For the safe and effective use of dental implants it is strongly suggested that specialised training be undertaken, including hands-on training to learn proper technique, biomechanical requirements and radiographic evaluations.
- Products must be secured against aspiration when handled intraorally. Aspiration of products may lead to infection or unplanned physical injury.

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. Implant failure increases when implants are placed in irradiated bone as radiotherapy can result in progressive fibrosis of vessels and soft tissue, leading to diminished healing capacity.

It is important to be aware and avoid damage to vital structures such as nerves, veins and arteries. Injuries to vital anatomical structures may cause serious complications such as injury to the eye, nerve damage and excessive bleeding. It is essential to protect the infraorbital nerve. Failing to identify actual measurements relative to the radiographic data could lead to complications.

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 orofacial 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 preoperative planning with a good team approach between well trained surgeons, restorative dentists and lab technicians is essential for successful implant treatment.
- minimising the trauma to the host tissue increases the potential for successful osseointegration.
- electrosurgery should not be attempted around metal implants as they are conductive.

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

Side effects

The side effects of the use of the system are not dissimilar to those of dental implant therapy. Possible side effects to implant therapy include:

- pain
- swelling
- phonetic difficulties
- gingival inflammation

Less common but more persistent symptoms include, but are not limited to:

- allergic reaction(s) to implant and/or abutment material
- breakage of the implant and/or abutment
- loosening of the abutment screw and/or retaining screw
- infection requiring revision of the dental implant
- nerve damage resulting in permanent weakness, numbness, or pain
- histologic responses with possible macrophage and/or fibroblast involvement

- fat emboli formation
- loosening of the implant requiring revision surgery
- perforation of the maxillary sinus
- perforation of the labial and lingual plates
- bone loss possibly resulting in revision or removal of the implant.

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.

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 peelback lid. Labelling information is located on the bottom half of the pouch or on the surface of the peel-back lid.

Restoration design restrictions

For the abutments, the following restoration design restrictions are applicable:

Design parameter	Limits to customisation
Minimum gingival height (mm)	0
Minimum wall thickness (mm)	0.22
Maximum angulation (°)	20
Minimum post height (mm)	4.5

For the SI-BASE Abutments, the following restoration design restrictions are applicable:

Implant/abutment interface	Design parameter	
	Minimum gingival diameter (mm)	Minimum diameter (mm)
Deep Conical Ø3.0 mm	4.1 or 4.5	4.1 or 4.5
Deep Conical Ø3.5/4.0 mm	4.3 or 4.8	4.3 or 4.8
Deep Conical Ø5.0 mm	5.5 or 6.5	5.5 or 6.5
External Hex Ø3.0 mm	4.1 or 4.5	4.1 or 4.5
External Hex Ø3.43 mm	4.3 or 4.8	4.3 or 4.8
External Hex Ø4.0 mm	5.0 or 5.5	5.0 or 5.5
External Hex Ø5.0 mm	5.5 or 6.5	5.5 or 6.5
External Hex Ø6.0 mm	6.5 or 7.5	6.5 or 7.5
External Hex Ø7.0 mm	7.5 or 8.0	7.5 or 8.0
PROVATA® Ø3.3 mm	4.1 or 4.5	4.1 or 4.5
Internal Hex (M-Series and PROVATA® Ø4.0/5.0 mm)	4.5 or 4.8	4.5 or 4.8
Internal Hex (M-Series Ø5.0 and PROVATA® Ø5.0/6.0) mm	4.8 or 5.5	4.8 or 5.5
Internal Hex (PROVATA® Ø6.0/7.0/8.0/9.0) mm	6.5 or 7.5	6.5 or 7.5
Internal Hex (PROVATA® Ø6.0/7.0/8.0/9.0) mm, platform matched	7.5	7.5

Tri-Nex® Ø3.5 mm	4.1	4.1
Tri-Nex® Ø4.3 mm	4.8	4.8
Compact conical Ø4.8 mm	5.2	5.2
Compact conical Ø6.0 mm	6.4	6.4

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 Titanium alloy (Ti-6AL-4V)

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 Metal Abutments	60095440387296

Related literature and catalogues

CAT-2004 – Tri-Nex® Implants Product 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-2063 – SIDigital Product Catalogue
CAT-2069 – INVERTA® Implants Product Catalogue
CAT-2070 – Zygomatic Implants Product Catalogue
CAT-2092 – Soft Bone 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 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.