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 worklflow: scan files from desktop/intraoral scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories. These abutments are supplied non-sterile and for single use only.

Intended use

Southern Implants® dental implant 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. SI-BASE abutments can be used in a CAD/CAM workflow.

Indications for use

The 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 mesostructured 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 devices are intended to be used in a clinical environment such as an operating theatre or a dentist consultation room.

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 of partial or full bridges, multi-unit cases and may be fixed or removeable.

Compatibility information

Southern Implants' implants should be restored with Southern Implants' components. In the Southern Implants' SI-BASE Abutment range there are 8 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)-(PD)(*) for engaging items
	Parts labelled SIB-NX-(Ø)-(PD)(*) for non-engaging items
TRI-NEX (EL) (Lobe)	Parts labelled SIB-EL-(Ø)-(PD)(*) for engaging items
	Parts labelled SIB-NL-(Ø)-(PD)(*) for non-engaging items
Deep Conical (DC)	Parts labelled SIB-DC(Ø)-(PD)(*) for engaging items Parts labelled SIB-DCR(Ø)-(PD)(*) for engaging items
	Parts labelled SIB-NDC(Ø)-(PD)(*) for non-engaging items
Internal Hex (M)	Parts labelled SIB-M-(PD)(*) for engaging items (used with Ø3.75mm, 4.20mm and 5.00mm platforms)
	Parts labelled SIB-NM-(PD)(*) for non-engaging items (used with Ø3.75mm, 4.20mm and 5.00mm platforms)
	Parts labelled SIB-M-PM-(PD)(*) for engaging items (used with Ø5.0mm platform)

Internal Hex PROVATA® (3M/M/Z)	Parts labelled SIB-3M-(PD)(*) for engaging items (used with Ø3.3mm platform)
	Parts labelled SIB-3NM-(PD)(*) for non-engaging items (used with Ø3.3mm platform)
	Parts labelled SIB-M-(PD)(*) for engaging items (used with Ø4.0mm, 5.0mm and 6.0mm platforms)
	Parts labelled SIB-NM-(PD)(*) for non-engaging items (used with Ø4.0mm, 5.0mm and 6.0mm platforms)
	Parts labelled SIB-M-PM-(PD)(*) for engaging items (used with Ø5.0mm and 6.0mm platforms)
	Parts labelled SIB-Z-(PD)(*) for engaging items (used with Ø6.0mm, 7.0mm, 8.0mm and 9.0mm platforms)
	Parts labelled SIB-NZ-(PD)(*) for non-engaging items (used with Ø6.0mm, 7.0mm, 8.0mm and 9.0mm platforms)
	Parts labelled SIB-Z-PM-(PD)(*) for engaging items (used with Ø8.0mm and 9.0mm platforms)
Internal Octagon IT (ITS/ITS6)	Parts labelled SIB-ITS-(PD)(*) (used with Ø4.8mm platforms for engaging items)
	Parts labelled SIB-ITSNE-(PD)(*) (used with Ø4.8mm platforms for non-engaging items)
	Parts labelled SIB-IT6-(PD)(*) (used with Ø6.5mm platforms for engaging items)
	Parts labelled SIB-IT6NE-(PD)(*) (used with Ø6.5mm platforms for non-engaging items)
Single Platform (SP1)	Parts labelled SIB-SP-(PD)(*) (used with Ø3.5, Ø3.75, Ø4.0, Ø4.5, Ø5.0, and Ø6.0 mm platforms for engaging items)
	Parts labelled SIB-NSP-(PD)(*) (used with Ø3.5, Ø3.75, Ø4.0, Ø4.5, Ø5.0, and Ø6.0 mm platforms for non-engaging items)
	Parts labelled SIB-SP-PM-(PD)(*) (used with Ø5.0, and Ø6.0 mm platforms for engaging items)
Abutment level (MC)	Parts labelled SIB-TMC1 (used with Ø4.8mm abutment platforms)
	Parts labelled SIB-TMCW1 (used with Ø6.0mm abutment platforms)

(PD) is indicative of the various abutment platform diameters available
(*) is indicative of various collar heights available

Digital workflow by using SIDIGITAL libraries

Scanning procedure (Intra-orally or using the 3Shape E3 Desktop Scanner)

1. Download Southern Implants digital library for 3Shape by registering on www.southernimplants.com/cad-cam-home/ and following the instructions as provided in the SIDigital Catalogue (downloaded from www.southernimplants.com).
2. Load the libraries into the CAD/CAM system by following their instructions.
3. The implant position is obtained digitally by an intraoral scan of the patient with scan flag attached to the endosseous implant, or a desktop scan of the dental model with the scan flag attached to the laboratory analogue.
4. Remove the scan flag from the implants or from the model.
   Replace healing abutments.
5. The scan is then imported into the design software.

Designing procedures

1. The scan flag in the digital form is now matched and aligned with the corresponding scan flag in the library.
2. The software recognises the position of the scan flag to the implant or analogue.
3. The SI-BASE abutment is chosen from the library.
4. The software will guide the user through the steps to complete the restoration.
5. Selection of the restorative material: the most common material to use is Zirconia.

Milling and sintering procedures (using WorkNC CAM software, Roland DWX51D Milling unit), SageMax NexxZr Zirconia, and Ivoclar Vivadent Multilink Hybrid abutment cement)

1. Follow the instructions for use of the CAD/CAM system and milling material being used.
2. The milled restoration is cemented to the prefabricated titanium SI-BASE abutment. Close the screw channel prior to cementing to keep the screw channel free of cement.

NOTE: please refer to the applicable OEM labeling and instructions for use of the compatible systems and tools referenced above, for the relevant installation, validation, maintenance and use-life guidelines.

Digital workflow by scanning directly without using digital libraries

Scanning procedures (Intra-orally)

1. Attach the SI-BASE abutment to the lab analogue on the master model and screw down with the appropriate laboratory screw and driver.
2. Temporarily cover the screw hole with wax.
3. Scan using usual scan routines.
4. The SI-BASE abutment is anodised gold and may not need scanning powder/spray to properly scan.

5. Scan using usual scan routines and design procedures.

Design and milling procedures

1. Attach the SI-BASE abutment to the lab analogue in the master model and screw down with the appropriate laboratory screw and driver.
2. Temporarily cover the screw hole with wax
3. Scan using scan routines.
4. The SI-BASE abutment is TiN coated and may not need scanning powder/spray to properly scan.
5. Scan using usual scan routines and design procedures.

Clinical procedures (placing restoration)

The clinician receives the restoration from the laboratory.

1. Remove the healing abutment or temporary restoration.
2. Clean, disinfect and sterilise the restoration as described.
3. Insert the restoration into the patient's mouth.
4. Position the restoration on the implant making sure that the retentive elements of the implant/abutment connections are properly aligned.

Table B – Driver Information

Driver type	External Hex	DC	Tri-Nex	Internal Hex	Single Platform (SP1)	IT	Compact Conical
1.22 mm / 1.27 mm Universal driver	✓	✓		✓	✓		✓
1.22 mm hex driver	✓	✓			✓		✓
1.27 mm hex driver				✓			
Unigrip driver	✓		✓				✓
Quad driver	✓			Gold screws only			
Blade driver	✓						✓
Torx Driver						✓	

5. Fix the abutment to the implant/abutment with the correct screw using applicable driver (Table B). Torque the screw down to the value indicated in Table C.

Table C – Prosthetic Screw Torque

SI-BASE abutment to Implant	Torque value
External Hex	
Ø3.0 mm	32 Ncm
Ø3.25, Ø4.0 mm	32-40 Ncm
Tri-Nex	
Ø3.5mm	32 Ncm
Ø4.3 mm, Ø5.0 mm, Ø6.0 mm	32-40 Ncm
DC	
Ø3.0 mm	20 Ncm
Ø3.5 and Ø4.0 mm	30 Ncm
Ø5.0 mm	32 Ncm
Internal Hex (M and PROVATA®)	
Ø3.3 mm	32 Ncm
Ø4.0 mm	32 Ncm
Internal Octagon (ITS/ITS6)	
Ø4.8, Ø6.5 mm	32-40 Ncm
Single Platform (SP1)	
Ø3.5, Ø3.75, Ø4.0, Ø4.5, Ø5.0, Ø6.0 mm	32 Ncm

Abutment level	All ASC Compact Conical abutments on Compact Conical abutments: 15 Ncm

6. Verify the correct seating of the restoration using radiographic image.

7. Do not exceed the recommended torque value as this may result in failure of the screw, abutment or implant. Do not torque less than the recommended value, this may result in loosening of the abutment that can lead to abutment or implant failure.
8. Close the screw access hole.
9. Cement the temporary prosthesis if applicable.

Clinical benefits

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

Before surgery

All components, instruments and tooling used during the clinical or laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

During surgery

Care must be taken that parts are not swallowed 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.

Storage, cleaning and sterilisation

The SI-BASE abutments are supplied non-sterile and 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.

NOTE: implants, cover screws, and healing abutments are supplied sterile (sterilised gamma irradiation) and intended for single-use prior to the expiration date (see packaging label). 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 single or multiple-tooth implant crown, bridge or substructure, attached to a Southern Implants®' abutment or multiple abutments. Before intraoral use the final restoration needs to be cleaned and disinfected, as per restorative material manufacturer's instructions.

Sterilisation

Southern Implants® recommends the following procedures to sterilise the restorations prior to use:

Methods to sterilise the restoration and abutment screw:

1. prevacuum sterilisation method: wrapped, steam sterilise at 135°C (275°F) 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, and 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.

Before surgery

All components, instruments and tooling used during the clinical or laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

During surgery

Care must be taken that parts are not swallowed 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.

Single use devices

Do not reuse devices indicated for single use (use the device prior to the expiration date).

Side effects

Potential side effects and temporary symptoms: pain, swelling, phonetic difficulties and 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 possible resulting in revision or removal.

As required by the European Medical Device Regulation (MDR; EU 2017/745), a summary of the Safety and Clinical Performance (SSCP)is available for perusal with regard to Southern Implants product ranges.

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

Breakage

Implant and abutment fractures can occur when applied loads exceed the tensile or compressive 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°, occlusal interferences causing excessive lateral forces, patient parafunction (e.g. bruxing or 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.

Healing

The healing time required for osseointegration depends on the individual and treatment protocol. It is the responsibility of the practitioner to device when the implant can be restored. Good primary stability will govern if immediate loading can be done.

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.

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).

Restoration design restrictions

For the SI-BASE abutments for the External Hex IP implant and the Ø3.0 Deep Conical Implant, 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 (°)	0
Minimum post height (mm)	4.5

For the remaining SI-BASE 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
Deep Conical platform-matched (DCR5)	5.5	5.5
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)	4.3 or 4.8	4.3 or 4.8
Internal Hex (M-Series Ø5.0 and PROVATA® Ø5.0/6.0) mm, platform matched	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® Ø8.0/9.0) mm, platform matched	7.5	7.5
Tri-Nex® Ø3.5 mm	4.3 or 4.8	4.3 or 4.8
Tri-Nex® Ø4.3 mm	4.5 or 5.5	4.5 or 5.5
Tri-Nex® Ø5.0 mm	5.5 or 6.5	5.5 or 6.5
Tri-Nex® Ø6.0 mm	6.5 or 7.5	6.5 or 7.5
Internal Octagon Ø4.8 mm	4.8 or 5.5 or 6.0	4.8 or 5.5 or 6.0
Internal Octagon Ø6.5 mm	6.5 or 7.5	6.5 or 7.5
Single Platform Ø3.5/4.0/5.0 mm	4.3 or 4.8	4.3 or 4.8
Single Platform Ø5.0 mm, platform matched	5.5 or 6.5	5.5 or 6.5
Single Platform Ø6.0 mm, platform matched	6.5 or 7.5	6.5 or 7.5
Compact conical Ø4.8 mm	5.2	5.2
Compact conical Ø6.0 mm	6.4	6.4

Digital workflow by using SIDIGITAL libraries

Scanning procedure

(Intra-orally or using the 3Shape E3 Desktop Scanner)

1. Download Southern Implants digital library for 3Shape by registering on www.southernimplants.com/cad-cam-home/ and following the instructions as provided in the SIDigital Catalogue (downloaded from www.southernimplants.com)
2. Load the libraries into the CAD/CAM system by following their instructions.
3. The implant position is obtained digitally by an intraoral scan of the patient with scan flag attached to the endosseous implant, or a desktop scan of the dental model with the scan flag attached to the laboratory analogue.
4. Remove the scan flag from the implants or from the model. Replace healing abutments.
5. The scan is then imported into the design software.

Designing procedures

1. The scan flag in the digital form is now matched and aligned with the corresponding scan flag in the library.
2. The software recognises the position of the scan flag to the implant or analogue.
3. The SI-Base abutment is chosen from the library.
4. The software will guide the user through the steps to complete the restoration.
5. Selection of the restorative material: the most common material to use is Zirconia.

Milling and sintering procedures

(using WorkNC CAM software, Roland DWX51D Milling unit, SageMax NexxZr Zirconia, and Ivoclar Vivadent Multilink Hybrid abutment cement)

1. Follow the instructions for use of the CAD/CAM system and milling material being used.
2. The milled restoration is cemented to the prefabricated titanium SI-Base abutment. Close the screw channel prior to cementing to keep the screw channel free of cement.

NOTE: please refer to the applicable OEM labelling and instructions for use of the compatible systems and tools referenced above, for the relevant installation, validation, maintenance and use-life guidelines.

Digital workflow by scanning directly without using digital libraries

Scanning procedure

(Intra-orally)

1. Attach the SI-Base abutment to the lab analogue on the master model and screw down with the appropriate laboratory screw and driver.
2. Temporarily cover the screw hole with wax.
3. Scan using usual scan routines.
4. The SI-Base abutment is anodised gold and may not need scanning powder/spray to properly scan.
5. Scan using usual scan routines and design procedures.

Design and milling procedure

1. Attach the SI-Base abutment to the lab analogue in the master model and screw down with the appropriate laboratory screw and driver.
2. Temporarily cover the screw hole with wax.
3. Scan using scan routines.
4. The SI-Base abutment is anodised gold and may not need scanning powder/spray to properly scan.
5. Scan using usual scan routines and design procedures.

Clinical procedures (placing restoration)

The clinician receives the restoration from the laboratory.

1. Remove the healing abutment or temporary restoration.
2. Clean, disinfect and sterilise the restoration as described.
3. Insert the restoration into the patient's mouth.
4. Position the restoration on the implant making sure that the retentive elements of the implant/abutment connections are properly aligned.

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

Titanium abutments:	Titanium alloy (Ti-6Al-4V); anodized gold
Abutment screws:	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

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 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.

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
Basic-UDI for Direct Abut. Titanium	6009544050117Q

Related literature and catalogues

CAT-2004 – Tri-Nex® Implants Product Catalogue
CAT-2005 – IT 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
CAT-2093 – Single Platform (SP1) 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.