English

# INSTRUCTIONS FOR USE: Southern Implants® Passive abutments



**South Africa - Headquarters:** 1 Albert Road, Irene, 0062, RSA
**T:** +27-12-667-1046 | **E:** info@southernimplants.com

EC REP
**Southern Implants Europe AB:** Holmgatan 30, S-791 71 Falun, Sweden
**T:** +46 23 13300 | **E:** ecrep@southernimplants.com

**Subsidiaries**

**Australia**
Southern Implants Australia
**T:** +61-(0)-8-9466-2627
**E:** info@southernimplants.com.au

**Spain and Portugal**
Southern Implants Iberica
**T:** +34 935 053 507
**E:** info@southernimplants.es

**United Kingdom and Ireland**
Southern Implants UK
**T:** +44-20-8899-6845 / 6 / 7
**E:** info@southernimplants.co.uk

**USA and Canada**
Southern Implants North America Inc.
**T:** +1-561-472-0990
**E:** customercare@southernimplants.com

## Description

The Southern Implants' prosthetic range consist of abutments or cylinders for prosthetic rehabilitation on the Southern range of implants. These are pre-manufactured and can be attached direct or indirect to the implant as an aid in prosthetic rehabilitation. These instructions apply to Passive abutments with burn out sleeves. These components are supplied non-sterile. A maximum of 20° angulation is allowed for angular correction on the prosthesis when using a Zirconia restoration designed using CAD/CAM procedures. For precious metal cast-on restorations, a maximum of 0° angulation is allowed for angular correction on the prosthesis.

## Intended use

This device is intended to treat partially or fully edentulous patients eligible for placement of one or more dental implants as a means of fixing a permanent or removable single crown, partial or full-arch dental prosthesis in the upper or lower jaw. The devices allow for immediate or delayed prosthetic restoration based on the user's evaluation of the patient's eligibility.
This device constituents are classified as medical devices and are intended for single use on a single patient.

## Indications for use

The Passive Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. The Passive abutments consist of two major parts. Specifically, the titanium base and mesostructure components make up a two-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.

## Intended user

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

## Intended environment

This device is intended to be used in a dental laboratory for making of the restoration and in a clinical environment such as an operating theatre or a dentist consultation room.

## Intended patient population

Patients that have lost one tooth or multiple teeth.

## Compatibility information

Southern Implants' implants should be restored with Southern Implants' components. In the Southern Implants' range there are 8 implant and abutment connections. The product code and connection type can be identified by specific abbreviations in the product codes. Range identifiers are summarised in Table A.

**Table A – Compatible abutments for implant ranges**

| Implant connection type | Compatible device |
|---|---|
| External Hex (EX) | Parts labelled SP16, SBN16, SB16, SBA16, SBBB16 and SMAX9H for engaging items |
| | Parts labelled SP17, SBN17, SB17, SBA17, SBBB17 and SMAX9NH for non-engaging items |
| TRI-NEX® (EL) (Lobe) | Parts labelled PA-EL-(Ø) for engaging items |
| | Parts labelled PA-NL-(Ø) for non-engaging items |
| Deep Conical (DC) | Parts labelled PA-DC-(Ø) for engaging items |
| | Parts labelled PA-NDC-(Ø) for non-engaging items |
| Internal Hex (M) | Parts labelled PA-EM-S (used with Ø3.75, 4.2 and 5.0 mm platforms) for engaging items |
| | Parts labelled PA-NM-S (used with Ø3.75, 4.2 and 5.0 mm platforms) for non-engaging items |
| Internal Hex PROVATA® (3M/ M/ Z) | Parts labelled PA-3EM-S (used with PROVATA® Ø3.3 mm platform) for engaging items |
| | Parts labelled PA-3NM-S (used with PROVATA® Ø3.3 mm platform) for non-engaging items |
| | Parts labelled PA-EM-S (used Ø4.0, 5.0 and 6.0 mm platforms) for engaging items |
| | Parts labelled PA-NM-S (used with Ø4.0, 5.0 and 6.0 mm platforms) for non-engaging items |
| | Parts labelled PA-EZ (used with Ø7.0, 8.0 and 9.0 mm platforms) for engaging items |
| | Parts labelled PA-NZ (used with Ø7.0, 8.0 and 9.0 mm platforms) for non-engaging items |
| Internal Octagon IT (ITS/ ITS6) | Parts labelled ITS-PA (used with Ø4.8 mm platforms) for engaging item |

| | |
|---|---|
| | Parts labelled ITS-PA-ne (used with Ø4.8 mm platforms) for non-engaging items |
| | Parts labelled ITS6-PA (used with Ø6.5 mm platforms) for engaging items |
| | Parts labelled ITS6-PA-ne (used with Ø6.5 mm platforms) for non-engaging items |
| Single Platform (SP) | Parts labelled PA-SP for (used with Ø3.5, 4.0 and 5.0 mm platforms) engaging items |
| | Parts labelled PA-NSP for (used with Ø3.5, 4.0 and 5.0 mm platforms) non-engaging items |
| | Parts labelled PA-SP-PM (used with Ø5.0 mm platforms) for platform-matched engaging items |
| Compact Conical Abutments | Parts labelled PA-MC-48 (used with Ø4.8 mm abutment platforms) for non-engaging items |
| | Parts labelled PA-MC-60 (used with Ø6.0 mm abutment platforms) for non-engaging items |

## Clinical benefits

Clinical benefits of dental implant therapy include improved chewing function, speech, aesthetics and patient psychological wellbeing. 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

Take care that parts are not swallowed or aspirated during any of the procedures and apply the correct tightening torque to abutments and abutment screws.

**CAUTION**: identify and protect vital structures like nerves, veins, arteries and especially the infraorbital nerve during surgical exposure of the lateral maxillary wall. Injury to any of these anatomical structures can lead to complications like nerve dysfunction or bleeding.

## Post-surgery

Regular patient follow-up and proper oral hygiene must be achieved to ensure favourable long-term results.

## 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: 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 oral surgical 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.

## Handling procedures for Traditional Workflows

### Surgical procedures

1. Use a model with removable soft tissue mask, allowing easy access to the analogues for lab procedures.
2. Finger-tighten the titanium interfacial component and plastic sleeve to the analogue with the laboratory screw. Use the corresponding driver as indicated in Table D. Do not over-tighten to avoid distortion of the plastic. The waxing sleeve can be cut back or added to as needed, with no additional angular correction allowable for precious metal cast-on restorations. The wax-up is completed and sprued on the model.

### Investing and casting

1. The retaining screw must be removed to allow the wax-up with plastic cylinders to be lifted from the model, leaving behind the loose titanium interfacial component.
2. Standard procedures are used for investing and casting. An appropriate casting alloy must be chosen, depending on whether a ceramic veneered bridge or cast bar is being manufactured. Alloys that are commonly used are: Degunorm, Argipal, Begopal 300, Begocer-G, Pors-on 4, Degudent G etc.
3. For complete burn-out: the plastic cylinder requires an oven temperature of 820°C for at least 45 minutes.
4. Devest ultrasonically as opposed to blasting with sand or glass beads. This helps preserve the sharp edges and fitting surfaces of the casting.

### Refining the screw seat

1. The screw seat is the internal ledge in the casting where the head of the screw will seat. The cast surface of the screw seat will be rough due to the casting process and must therefore be refined using special hand-held reamers as indicated in Table B. The correct diameter of reamer must be chosen. This is an important step to ensure proper seating and tightening of the final prosthetic screw.

**NOTE**: do not sandblast the titanium interfacial component.

### Table B – Reamers

| Reamer diameter (mm) | Reamer Code | Use with | Screw head diameter (mm) |
|---|---|---|---|
| 2.2 | LT18-2.2 | TS-DC3-MC | 2.0 |
| | | TS-DC4-MC | |
| | | TS-SSP-MC | |
| | | TS-DC3-14 | 2.10 |
| | | TS-P-16 | 2.15 |
| | | TSS4 | 2.20 |
| | | GSH4 | |
| | | PA-DC3-14T | |
| | | TS-Z-MC-18 | |
| | | TS-Z-MC-16 | |
| | | PA-M-16T | |
| 2.3 | LT18-2.3 | TSH1 | 2.25 |
| | | TSU1 | |
| | | TSS1 | |
| | | GSH1 | |
| | | GSU1 | |
| | | GSS1 | |
| | | TU-MCL-18C | |
| | | GU-MCL-18 | |
| | | TS-Z-18 | |

| | | | |
|---|---|---|---|
| | | GS-Q-18 | |
| | | TS-DC4-16 | 2.30 |
| | | TS-Z-16 | |
| 2.4 | LT18-2.4 | TS-DC5-20 | 2.35 |
| | | TSHZ3 | 2.40 |
| | | PA-SP-16T | |
| | | TSUZ3 | |
| | | TSSZ3 | |
| | | TSU3 | |
| | | TSS3 | |
| | | GSUZ3 | |
| | | GSQZ3 | |
| | | GSSZ3 | |
| | | GSS3 | |
| | | GSU3 | |
| | | GSQ3 | |
| | | TS-IT-TIB | |
| | | PA-DC4-16T | |
| 2.6 | LT18-2.6 | TU-MCL-20C | 2.45 |
| | | GU-MCL-20 | |
| | | TSUZ9 | 2.50 |
| | | TSU9 | |
| | | GSUZ9 | |
| | | GSU9 | |
| | | TS-L-18 | |
| | | TS-L-18C | |
| | | GS-L-18 | |
| | | TS-L-20 | |
| | | TS-L-20C | |
| | | GS-L-20 | |
| | | PA-M-18T | 2.60 |
| | | PA-Q-18G | |
| 2.8 | LT18-2.8 | TSHZ2 | 2.70 |
| | | TSUZ2 | |
| | | TSU2 | |
| | | TSSZ2 | |
| | | TSS2 | |
| | | GSUZ2 | |
| | | GSQZ2 | |
| | | GSSZ2 | |
| | | GSIT2 | |
| | | GSS2 | |
| | | GSU2 | |
| | | GSQ2 | |
| | | TSIT2 | |
| | | TS-IT-PA | |
| | | PA-L-18 | |
| | | PA-L-18G | |
| | | PA-L-20 | |
| | | PA-L-20G | |
| 2.9 | LT18-2.9 | PA-DC5-20T | 2.80 |



**Luting procedures for Passive abutments**

The luting procedure and concept stays the same when using Passive abutments on compact conical level, multiple unit restorations and single unit restorations. The following steps are applicable to all.

1. It is important to ultrasonically clean or steam clean the following before the luting procedure starts:
   - the titanium interfacial components.
   - the luting screws.
   - the fitting surfaces of the prosthesis.
   - clean the analogues in the model by brushing with soap and water or steam clean to remove any debris which may interfere with perfect seating of the interfacial components.
2. Finger-tighten (with the PEEK luting screw) the titanium interfacial component to the laboratory analogue. Use the corresponding driver as indicated in Table C.
3. The sleeve can easily be fitted and removed from the titanium interfacial component without the need to remove or replace the PEEK luting screw. This is due to the PEEK luting screw attaching the titanium

interfacial component to the analogue and not the structure to the analogue. The PEEK luting screw can be removed and a laboratory screw can be used to attach the prosthesis to the master model. This will ensure that the prosthesis does not move during articulation, opposite set up, or any other laboratory procedures.

4. Clean the restoration in an ultrasonic unit for about 1 minute. Dry with oil-free air. Apply a bonding agent like Monobond Plus (Ivoclar Vivadent) to the cleaned surfaces of the titanium interfacial component and restoration using a small brush. Allow the Monobond Plus to react for 60 seconds and disperse with compressed air.
5. Lute the titanium interfacial abutment to the structure by applying a self-cure resin cement or dual cure resin cement (e.g. Rely X by 3M) to the surface of all of the titanium interfacial components.

**Table C – Luting Screws**

| Driver Type | External Hex | DC | Tri-Nex® | Internal Hex | IT | Single Platform | Compact Conical Screw |
|---|---|---|---|---|---|---|---|
| 0.90 mm | | DC3 only | | | | | ✓ |
| 1.22 mm/1.27 mm Universal driver | ✓ | ✓ | | ✓ | ✓ | ✓ | |
| 1.22 mm hex driver | ✓ | ✓ | | | ✓ | ✓ | |
| 1.27 mm hex driver | | | | ✓ | | | |
| Unigrip driver | | | ✓ | | | | |
| Quad driver | | | | | | | |
| Blade driver | | | | | | | |
| Torx driver | | | | | | | |

**NOTE**: refrigeration of self-cure resin cements will usually lengthen working time for ease of use on multi-unit structures. Limit the amount of resin cement being applied to the angle between the horizontal plane and vertical plane of the titanium interfacial component. This will avoid excess cement extruding upwards through the screw hole in the structure and inadvertently locking the luting screw into the cement. Definitely avoid placing any cement in the area immediately around the head of the luting screw.

**NOTE**: in the event that cement locks the luting screw in position, a Ø1.5 mm round burr is rotated into the hex of the screw. This separates the screw head from the shaft and frees the prosthesis. Take care not to damage the components. The prosthesis can then be removed.

6. Fit the prosthesis over the titanium interfacial component and settle the prosthesis firmly into place with finger pressure to extrude excess cement. Arch structures can be left seated under their own weight to allow cement to harden.
7. Light cure for 60 seconds.
8. Un-mount the restoration and remove excess cement using a sharp blade, probe or hand scaler instrument to make polishing easier.
9. Once resin cement has hardened, remove all luting screws and then remove any prosthetic retaining screws so that the prosthesis can be lifted from the model.
10. Attach polishing protectors to each of the fitting surfaces of the cemented titanium interfacial component. Polish the remaining cement line using a fine-edged lens-shaped rubber wheel. The cement line is often not of constant thickness. This variation is indicative of the extent of misfit which existed and has now been corrected by the cement space of the Passive Abutment.

## Handling procedures for Digital Workflows using SIDigital libraries

### Scanning procedures (the 3Shape E3 desktop Scanner)

1. Download Southern Implants digital library for 3Shape by registering on www.southernimplants.com.
2. Load the libraries into the CAD/CAM system by following their instructions.
3. Attach the scan flag to the lab analogue on the master model and screw down with the appropriate laboratory screw and driver.
4. Scan using usual scan routines.
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 Passive 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 Passive 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.

## Clinical procedure (for traditional and digital workflows)

The clinician receives the restoration from the laboratory.

1. Remove the healing abutment or temporary restoration.
2. Clean, disinfect and sterilise the restoration.
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.
5. Fix the abutment to the implant with the correct screw using the applicable driver (Table D), torque the screw down to the value indicated in Table E.
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.

**Table D – Retaining Screws**

| Driver Type | External Hex | DC | Tri-Nex® | Internal Hex | IT | Single Platform | Compact Conical Screw |
|---|---|---|---|---|---|---|---|
| 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 | ✓ | | | | ✓ | | ✓ |

**Table E – Torque Values**

| Direct to Implant | Torque |
|---|---|
| External Hex | |
| Ø3.0 mm | 25-32 Ncm |
| Ø3.25, 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 mm | 32-40 Ncm |
| Tri-Nex® | |
| Ø3.0 mm | 30 Ncm |
| Ø4.3, 5.0, 6.0, 7.0, 8.0 and 9.0 mm | 32-40 Ncm |
| Deep Conical | |
| Ø3.0 mm | 15 Ncm |
| Ø3.5 and 4.0 mm | 20 Ncm |
| Ø5.0 mm | 25-32 Ncm |
| Internal Hex (M-Series & PROVATA®) | |
| Ø3.75, 4.2 and 5.0 mm M-Series | 32 Ncm |
| Ø3.3, 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 mm PROVATA® | 32 Ncm |
| IT Octagon | |
| Ø3.3, 4.1, 4.9, 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 mm | 32-40 Ncm |
| Single Platform (SP1) | |
| Ø3.5, 4.0 and 5.0 mm | 32 Ncm |
| Abutment level | |
| All Passive abutments on Compact Conical abutments | 10-15 Ncm |

## 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

The limits of customization for the Passive abutments are shown in the following table.

| Design Parameter | Limits to customisation |
|---|---|
| Minimum wall thickness (mm) | No customization allowed |
| Minimum gingival margin diameter (mm) | No customization allowed |
| Minimum gingival margin height (mm) | No customization allowed |
| Total height (mm) | Do not shorten to exceed the limit of the abutment post height. |
| Minimum abutment post height (above gingival collar) (mm) | Do not shorten the abutment post height to less than 4 mm. |
| Maximum angulation (°) | Digital workflow with Zirconia restoration:<br>Maximum 20° angulation allowed |
| | Traditional workflow with precious metal Cast-on restoration:<br>Maximum 0° angulation allowed |

## 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

| | |
|---|---|
| Passive abutment | Commercially Pure Titanium (Grade 4, Grade 2 or Grade 3), Titanium Alloy (Ti-6Al-4V) |
| Plastic sleeve | Polyoxymethylene (POM) |
| Luting screw | Medical grade PEEK (polyetheretherketone) |
| Abutment screws | Titanium alloy Ti-90%, Al-6%, V-4%; Gold Alloy Au-61%, Ag-16.5%, Pt-13.5%, Cu-9% |

## 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-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-2069 - INVERTA® Implants Product Catalogue
CAT-2070 - Zygomatic 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.