SOUTHERNIMPLANTS®
Innovative Treatment Solutions

English	**INSTRUCTIONS FOR USE: Southern Implants® PEEK Temporary abutments.**
Español	**INSTRUCCIONES DE USO: Pilares temporales PEEK Southern Implants®.**
Italiano	**ISTRUZIONI PER L'USO: Southern Implants® Monconi provvisori in PEEK**
Français	**MODE D'EMPLOI : Piliers temporaires PEEK Southern Implants®.**
Deutsch	**GEBRAUCHSANWEISUNG: Southern Implants® temporäre PEEK-Abutments.**
Português	**INSTRUÇÕES DE UTILIZAÇÃO: Pilares temporários PEEK da Southern Implants®.**

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Intended use
Southern Implants® PEEK Temporary Abutments are intended to be used in the Maxilla or Mandible for supporting a temporary prosthesis on endosseous implants in order to restore chewing function for the patient. The PEEK temporary abutments are attached to the implants by a retention screw made from Titanium alloy. The PEEK abutments are medical devices. The PEEK abutments are intended for single use on a single patient.

Intended user
Maxillo-facial Surgeons, General Dentists, Orthodontists, Periodontist, Prosthodontists and other appropriately trained and experienced implant users.

Intended environment
The PEEK abutments are intended to be used in a clinical environment such as an operating theater 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 single teeth, partial or full bridges, and may be fixed or removable.

Description
PEEK abutments are premanufactured and are available in a variety of connections, engaging and non-engaging, to fit the implant systems manufactured by Southern Implants. They are used as an aid in manufacturing a prosthesis for prosthetic rehabilitation. They can either be used for direct connection to an endosseous implant, or they can be used for connecting the prosthesis to a compact conical abutment.

PEEK abutments are available in a 2 mm collar heights direct to implant, and 1 mm collar on abutment level and IT implants. The PEEK abutments are provided sterile; however, it will no longer be sterile after modification.

Indications for use
The Southern Implants PEEK Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation.

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, iridium or polyetheretherketone (PEEK)
- 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.

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.

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.

Compatibility information
SI Implants should be restored with SI components. In the SI 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

Implant connection type	Compatible device
External Hex (EX)	Parts labelled PKIP2H, PKBN2H, PKB2H, PKBA2H, PKBBB2H, PKMAX9-2H for engaging items
	Parts labelled PKIP2NH, PKBN2NH, PKB2NH, PKBA2NH, PKBBB2NH, PKMAX9-2NH for non-engaging items
Tri-Nex (EL) (Lobe)	Parts labelled PKC-EL-(ø), for engaging items
	Parts labelled PKC-NL-(ø), for non-engaging items
Deep Conical (DC)	Parts labelled PKC-DC-(ø), for engaging items
	Parts labelled PKC-NDC-(ø), for non-engaging items
Internal Hex (M)	Parts labelled PKC-M-2, (used with ø3.75,4.2 & 5.0 mm platforms) for engaging items
	Parts labelled PKC-NM-2, (used with ø3.75,4.2 & 5.0 mm platforms) for non-engaging items

Internal Hex Provata (M) (Z)	Parts labelled PKC-M-2, (used with ø4.0, 5.0, 6.0 mm platforms) for engaging items
	Parts labelled PKC-NM-2, (used with ø4.0, 5.0, 6.0 mm platforms) for non-engaging items
	Parts labelled PKC-Z-2, (used with ø7.0, 8.0 & 9.0 mm platforms) for engaging items
	Parts labelled PKC-NZ-2, (used with ø7.0, 8.0 & 9.0 mm platforms) for non-engaging items
IT (ITS) (ITS6)-Octagon	Parts labelled ITS-PKC1 (used with ø4.8 mm platforms) for engaging items
	Parts labelled ITS6-PKC1 (used with ø6.5 mm platforms) for engaging items
Abutment level	Parts labelled PKC-MC (used with ø4.8 mm abutment platforms) non-engaging
	Parts labelled PKC-MCW (used with ø6.0 mm abutment platforms) non-engaging

Storage, cleaning & sterilisation

The implants, cover screws and healing abutments are supplied sterile (sterilised by gamma irradiation) and intended for single-use prior to the expiration date (see packaging label). Sterility is assured unless the container or seal is damaged or opened. If packaging is damaged do not use the product and contact your Southern representative/ or return to Southern Implants. 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.

Sterilisation

Southern Implants recommends the following procedure to sterilise the restoration prior to use:

Methods to sterilise the restoration and abutment screw

1. Pre-vacuum sterilisation method: Steam sterilise the abutments at 132°C (270°F) at 180-220kPa 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. Pre-vacuum 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.

Chairside procedure (making a temporary restoration)

Note: Modification of PEEK abutments can be done with a carbide burr or disk. It is recommended to do this extra orally and with copius irrigation during cutting.

1. Shape the abutment to the correct occlusal height, with no additional angular correction. Do not reduce to below a minimum height of 4 mm, measured from the implant (or Compact Conical abutment) interface.
2. Connect the abutment to the implant with the correct prosthetic screw and driver (sold separately). Do not exceed the recommended torque.
3. Close the screw channel hole in a way that will ensure the prosthetic screw can be retrieved.
4. Make a temporary restoration by using a pre-formed stent and suitable temporary material.
5. Unscrew the temporary prosthesis.
6. Make final adjustments.
7. Clean and disinfect the restoration as applicable per the restorative material manufacturer's instructions.
8. Fix the PEEK abutment to the implant / compact conical abutment with the correct screw and appropriate driver Table B. Torque the screw down to the value indicated in Table C.

Laboratory procedures

The laboratory receives the impression from the clinician, either implant or abutment level.

1. The corresponding laboratory analogue is connected to the impression coping. Fabricate a working model with removable gingival mask or soft tissue material.
2. Follow the same steps 1- 6 as for the clinical procedure to construct the temporary restoration.

Clinical procedures

The clinician receives the restoration from the laboratory.

1. Remove the healing abutment.
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 type	External Hex	DC	Tri-Nex	Internal Hex	IT	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					✓	

5. Fix the PEEK abutment to the implant / compact conical abutment with the correct screw and appropriate driver Table B. Torque the screw down to the value indicated in Table C

Table C

Direct to Implant	Torque
Ext-Hex	
ø3.0, 3.25 mm	15 Ncm
ø4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 mm	20 Ncm
Tri-Nex	
ø3.5mm	15 Ncm
ø4.3, 5.0, 6.0, 7.0, 8.0 and 9.0 mm	20 Ncm
DC	
ø3.0 mm	15 Ncm
ø3.5, 4.0 mm	20 Ncm
ø5.0 mm	20 Ncm

Internal Hex (M-Series & Provata)	
ø3.75, 4.2, 5.0 mm M-Series	15 Ncm
ø4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 mm Provata Implant	15 Ncm
IT Octagon	
ø3.3, 4.1, 4.9, 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 mm IT Implant	20 Ncm

Abutment level	All PEEK Abutments on Compact Conical Abutments: 15 Ncm

6. 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.
7. Close the screw access hole.
8. Cement the temporary prosthesis

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

Healing
The healing time required for osseointegration depends on the individual and treatment protocol. It is the responsibility of the practitioner to decide 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.

Materials
PEEK: Polyetheretherketone (PEEK)
Abutment screws: Titanium alloy Ti-90%, Al-6%, V-4%,

Side effects
Potential Side Effects and Temporary symptoms: Pain, swelling, phonetic difficulties, 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 possibly resulting in revision or removal.

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 degrees, occlusal interferences causing excessive lateral forces, patient parafunction (e.g., bruxing, 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.

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).

MR Conditional
Non-clinical testing and MRI simulations were performed to evaluate the dental implant system offered by Southern Implants. Non-clinical testing demonstrates that these products are MR Conditional. A patient with an implant from a Southern Implants System can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla only
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m)
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2 W/kg and head average SAR of 3.2 W/kg, for 15 minutes of scanning (i.e., per pulse sequence) in the normal operating mode

The scanning conditions defined above will produce a maximum temperature increase of 4.9 °C in implants from Southern Implants systems after 15 minutes of continuous scanning (i.e., per pulse sequence).
In non-clinical testing, the image artifact caused by implants from Southern Implant System extends approximately 10 mm from this device when imaged with a gradient echo pulse sequence and a 3 Tesla MR system.

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.

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.

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

Basic UDI

Product	Basic-UDI Number
Basic-UDI for Peek Abutments	600954403874

Related literature & 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-2070- Zygomatic Implants Product Catalogue

Symbols and Warnings

* 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.