English

INSTRUCTIONS FOR USE: Southern Implants® PEEK Anatomical Healing Abutments

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Description

The Southern Implants® PEEK Anatomic Healing Abutments (AHA®) are premanufactured and available for External Hex (Standard & MAX), TRI-NEX (TRIMAX), Deep Conical (DC) and PROVATA® (PROMAX) Implant systems, as a temporary aid in prosthetic rehabilitation. These abutments are customisable to each patient and are provided sterile; however, it will no longer be sterile after modification.

Intended use

Southern Implants dental 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. Healing abutments are intended to be used as a temporary component to an endosseous implant to allow healing of the soft tissue after surgery.

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.

Intended user

Dental Technicians, Maxillofacial Surgeons, General Dentists, Orthodontists, Periodontists, Prosthodontists, and other appropriately trained and/or experienced medical professionals.

Intended environment

The devices are intended to be used in a dental laboratory as part of the restoration design and manufacture as well as in a clinical environment such as an operating theatre or a dentist consultation room.

Intended patient population

The device is intended to be used in partially or fully edentulous patients eligible, or otherwise not contraindicated, for implant-retained prosthetic dental restorations.

Compatibility information

Southern Implants' implants should be restored with Southern Implants' components. The Southern Implants' PEEK Anatomical Healing Abutments range includes abutments for 4 implant connections. The implant code and connection type can be identified by specific abbreviations in the product codes. Range identifiers are summarised in Table 1.

Table 1

Implant connection	Product code (non-radio opaque)	Product code (radio opaque)	Compatible Implant/implant connection	Screw	Hand held Drivers	Handpiece drivers	Wrench insert drivers
External Hex	PK-MAX7-9	PKR-MAX7-9	MAX7 implant	TSSZ3 (slotted) TSUZ3 (unigrip) TSHZ3 (hex)	I-BD (slotted) I-UGI (Unigrip) I-HD (hexed)	I-HBDS (slotted) I-HUG (Unigrip) I-HHD-22 (hexed)	I-WI-B (slotted) I-WI-UG (Unigrip) I-WI-22 (hexed)
	PK-MAX7-11	PKR-MAX7-11	MAX7 implant				
	PK-MAX8-11	PKR-MAX8-11	MAX8 implant				
	HA-PKC1-EX-30	HA-PKR1-EX-30	Ø3.0 mm platform	TS-P-16			
	HA-PKC2-EX-30	HA-PKR2-EX-30					
	HA-PKC1-EX-34	HA-PKR1-EX-34	Ø3.25 mm platform	TSSZ3 (slotted) TSUZ3 (unigrip) TSHZ3 (hex)			
	HA-PKC2-EX-34	HA-PKR2-EX-34					
	HA-PKC3-EX-34	HA-PKR3-EX-34					
	HA-PKC4-EX-34	HA-PKR4-EX-34					
	HA-PKC1-EX-40	HA-PKR1-EX-40	Ø4 mm platform				
	HA-PKC2-EX-40	HA-PKR2-EX-40					
	HA-PKC3-EX-40	HA-PKR3-EX-40					
	HA-PKC4-EX-40	HA-PKR4-EX-40					

Deep Conical	HA-PKC1-DC3	HA-PKR1-DC3	Ø3.0 mm platform	TS-DC3-14	I-HD (hexed) I-HD-22U (hexed)	I-HHD-22 (hexed) I-HHD-22U (hexed)	I-WI-22 (hexed) I-WI-22U (hexed)
	HA-PKC2-DC3	HA-PKR2-DC3					
	HA-PKC1-DC4	HA-PKR1-DC4	Ø4.0 mm platform	TS-DC4-16			
	HA-PKC2-DC4	HA-PKR2-DC4					
	HA-PKC3-DC4	HA-PKR3-DC4					
	HA-PKC4-DC4	HA-PKR4-DC4					
	HA-PKC1-DC5	HA-PKR1-DC5	Ø5.0 mm platform	TS-DC5-20			
	HA-PKC2-DC5	HA-PKR2-DC5					
	HA-PKC3-DC5	HA-PKR3-DC5					
	HA-PKC4-DC5	HA-PKR4-DC5					
Tri-Nex	PK-MAX6-9	PKR-MAX6-9	TRI-MAX6 implant	TS-L-20	I-UGI	I-HUG	I-WI-UG
	PK-L-MAX7-9	PKR-L-MAX7-9	TRI-MAX7 implant				
	PK-L-MAX7-11	PKR-L-MAX7-11	TRI-MAX7 implant				
	PK-L-MAX8-9	PKR-L-MAX8-9	TRI-MAX8 implant				
	PK-L-MAX8-11	PKR-L-MAX8-11	TRI-MAX8 implant				
Internal Hex	PKA-M-PM6-9	-	PROMAX6 implant	TS-Z-18	I-HD-27	I-HHD-27	I-WI-27
	PKA-Z6-9	PKR-Z6-9	PROMAX7 implant PROMAX8 implant PROMAX9 implant				
	PKA-Z9-10	-					
	PKA-Z8-11	PKR-Z8-11					

Table 2 summarises the recommended screw torque values of the Southern Screws when used with the PEEK Anatomical Healing Abutments. See CAT-8068 – Prosthetic Screws Instructions for Use.

Table 2

Range	Screw type	Torque
External Hex (EX)	3 Series (TSSZ3, TSUZ3, TSHZ3)	< Ø4.0 mm implant interfaces: 15 Ncm ≥ Ø4.0 mm implant interfaces: 20 Ncm
	TS-P-16	15 Ncm
Tri-Nex (EL)	TS-L-20	20 Ncm
Deep Conical (DC)	TS-DC3-14	15 Ncm
	TS-DC4-16	20 Ncm
	TS-DC5-20	20 Ncm
Internal Hex (PROVATA®)	TS-Z-18	15 Ncm

Clinical performance

The PEEK Abutments are intended to seal the implant connection and create a stable environment that fosters the integration of the implant into the surrounding bone and the healing of the soft tissue. Consequently, the clinical performance of the PEEK Abutments is primarily defined by their effectiveness in facilitating osseointegration and promoting optimal soft tissue healing. This performance can be quantitatively assessed through rates of successful osseointegration, the health of the peri-implant soft tissue, the incidence of soft tissue irritation, and the emergence profile established by the healing abutments.

Clinical benefits

Due to their role in the healing phase of dental implant therapy, the Southern Implants® PEEK Abutments provide clinical benefits associated with the enhancement of peri-implant soft tissue health and the improvement of aesthetic outcomes for the final restoration. Additionally, due to their intrinsic link with the overall success of the treatment, these abutments indirectly afford the benefits associated with the overall treatment, reflecting their contribution to the overall treatment system. These indirect benefits can be assessed through treatment success rates, patient satisfaction metrics and improvements in quality of life.

Storage, cleaning and sterilisation

The component is 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®. The devices must be stored in a dry place at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics. Do not reuse components indicated for single-use only. Reusing these components may result in:

- damage to the surface or critical dimensions, which may result in performance and compatibility degradation.
- adds the risk of cross-patient infection and contamination if single-use items are reused.

Southern Implants® does not accept any responsibility for complications associated with reused single-use components.

Sterilisation

Southern Implants® recommends one of the following procedures to sterilise the restorations 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.
- who are allergic or have hypersensitivity to polyetheretherketone (PEEK).
- where adequate numbers of implants could not be placed to achieve full functional support for a prosthesis.

Warnings

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.
- 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, periodontal status, and adequacy of bone.
    - 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, thus 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 are essential for favourable long-term results.

Procedure for use:

1. Select appropriate healing abutment and shape it to the desired emergence profile and height using a rotary burr.
2. Connect abutment to the implant using the recommended prosthetic screw and driver (refer to Table 1).
3. Rotate the abutment to the desired orientation and tighten the prosthetic screw to the recommended torque (refer to Table 2).

Side effects

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

- Abutment fracture
- Allergic reaction(s) to the abutment material
- Bruising
- Complications requiring revision surgery
- Discomfort
- Gingival inflammation
- Gingival recession
- Hematoma or bruising
- Hyperplastic tissue response
- Infection (acute and/or chronic)
- Localized inflammation
- Misfit or improper connection at the implant-abutment interface
- Overloading of the abutment/implant
- Pain, tenderness or discomfort
- Peri-implantitis, peri-mucositis or otherwise poor peri-implant soft tissue health
- Periodontal inflammation
- Phonetic difficulties
- Soft tissue irritation
- Wound dehiscence or poor healing

Additionally, the normal side effects associated with anaesthesia should also be expected.

Precaution: maintaining sterility protocol

The abutments 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.

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

Abutment Material Type	White Medical Grade polyether ether ketone (PEEK)
Abutment Screws Material Type	Titanium alloy (Ti-6Al-4V) according to ASTM F136 and ISO 5832-3

Titanium alloy (Ti-6Al-4V) according to ASTM F136 and ISO 5832-3

Chemical Components	Aluminium (Al)	Vanadium (V)	Residuals* (Fe, O, C, N, H) in total	Titanium (Ti)
Composition, % (mass/mass)	5.50 – 6.75	3.50 – 4.50	<0.55	Balance

*Where, Fe = Iron, O = Oxygen, C= Carbon, N = Nitrogen, H = Hydrogen

Disposal

Disposal of the device and its packaging: follow local regulations and environmental requirements, taking different contamination levels into account. When disposing of spent items, take care of sharp drills and instruments. Sufficient PPE must be used at all times.

Magnetic Resonance (MR) Safety

This device has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artefact in the MR environment. The safety of this device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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 PEEK Abutments	60095440038749A
Basic-UDI for Prosthetic Screws Titanium	60095440501886

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-2092 - Soft Bone Implants Product Catalogue
CAT-2093 - Single Platform Implants Product Catalogue
CAT-2095 - External Hex INVERTA Implants Product Catalogue
CAT-2096 - External Hex PTERYGOID Implants Product Catalogue

CAT-8068 – Prosthetic Screws Instructions for Use

Symbols and warnings


Manufacturer

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.