SOUTHERNIMPLANTS®
Innovative Treatment Solutions

English	INSTRUCTIONS FOR USE: Southern Implants® AHA Abutments®
Español	INSTRUCCIONES DE USO: Southern Implants® AHA Abutments®
Italiano	ISTRUZIONI PER L'USO: Southern Implants® AHA Abutments®
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Deutsch	GEBRAUCHSANWEISUNG: Southern Implants® AHA Abutments®
Português	INSTRUÇÕES DE UTILIZAÇÃO: Southern Implants® AHA Abutments®

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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. The PEEK abutments are medical devices. The PEEK abutments are intended for single use on a single patient.

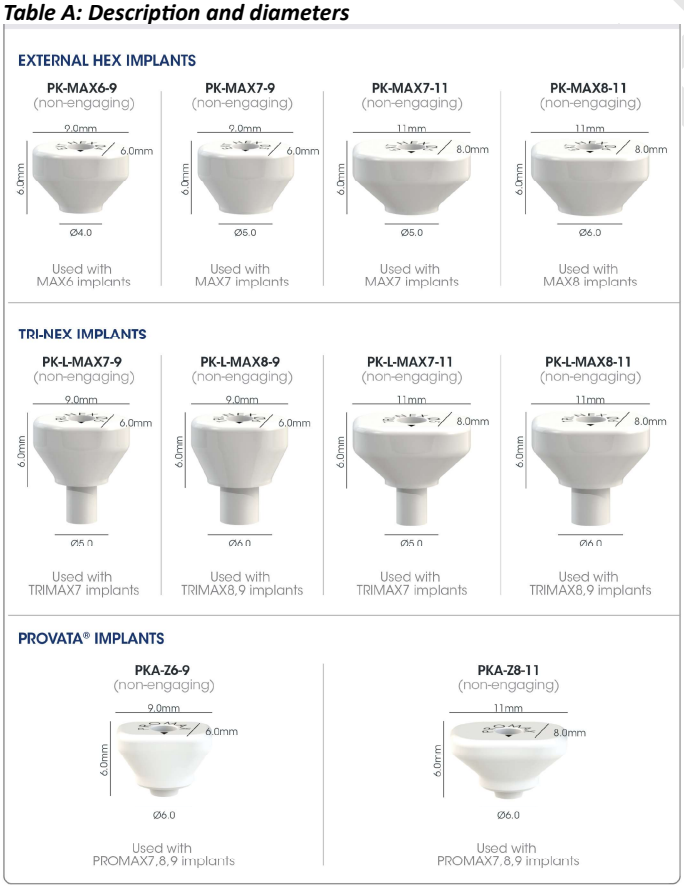
Intended user
Maxillo-facial Surgeons, General Dentists, Orthodontists, Periodontist, Prosthodontists and other appropriately trained and experienced implant users.

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

Table A: Description and diameters



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. The AHA abutments are available for MAX, PROMAX and TRI-MAX as indicated in Table A.

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 (Customising the temporary abutment)

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

1. The morphology of the AHA abutment has been designed in consideration of typical molar and premolar morphologic dimensions published in the literature. Choose the AHA abutment with the closest dimensions of the patients missing molar or pre-molar “crown”.
2. Shape the AHA abutment to the correct occlusal height, do not reduce to below a minimum height of 4 mm, measured from the implant platform. Also shape the abutment in a mesio/distal and lingual/labial direction to get the most desired emergence profile for soft tissue development. The AHA abutment can be attached to a policing protector cap or laboratory analogue to ensure the fitting surface between the abutment and the implant is not damaged.
3. Smooth and polish the customised AHA abutment.
4. Clean and disinfect the restoration as applicable per the restorative material manufacturer’s instructions.
5. Connect the AHA abutment to the implant with the correct prosthetic screw and driver (sold separately) Table B. Do not exceed the recommended torque of 20Ncm.
6. Close the screw channel hole in a way that will ensure the prosthetic screw can be retrieved.

Table B

Driver type	External Hex	Tri-Nex	PROVATA
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			

7. After 3 months the AHA abutment is removed and the osseointegration of the implant is verified, and the final restoration placed.

Note: 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

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).

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

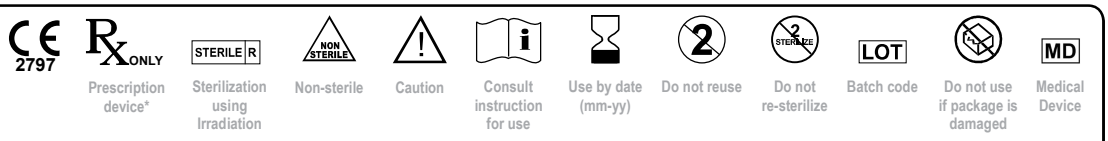
Basic UDI

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

Related literature & catalogues

CAT-2020- External Hex Implants Product Catalogue
CAT-2004- Tri-Nex Implants Product Catalogue
CAT-2060- PROVATA® 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.