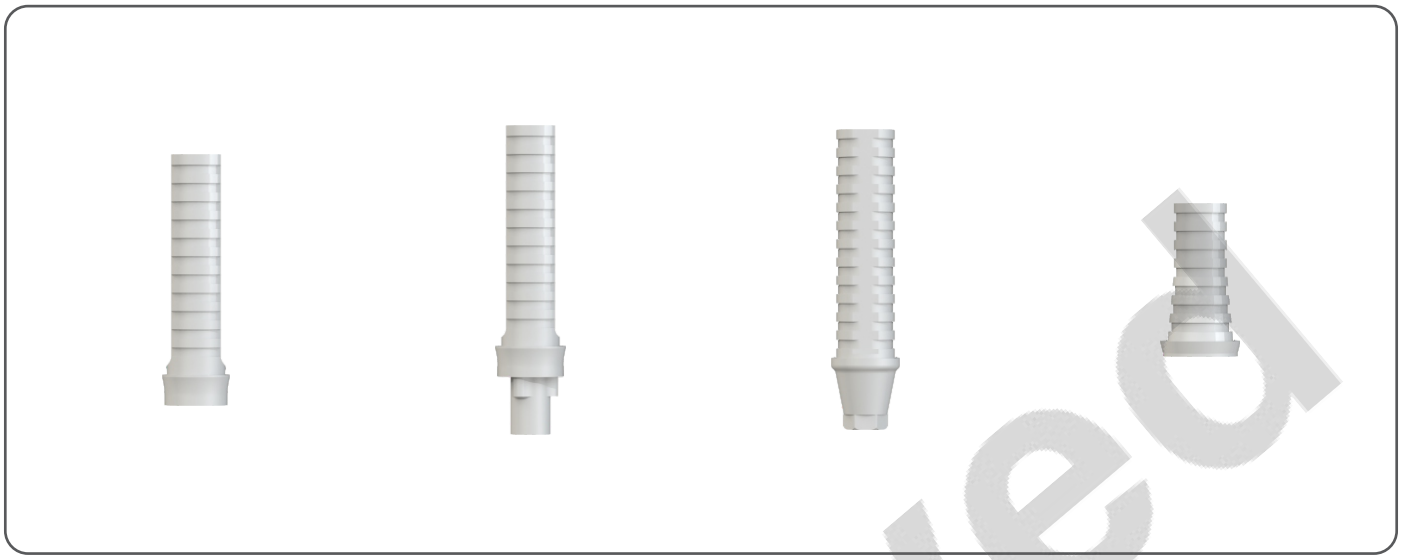
# INSTRUCTIONS FOR USE:
# PEEK Cylinders



## Intended use:

Dental implant abutments are intended to be used in the Maxilla or Mandible for supporting the prosthesis on endosseous implants in order to restore chewing function for the patient.

## Description:

PEEK abutments are pre-manufactured and are available in different connections, collar heights, engaging and non-engaging versions. (Refer to Figure1). These abutments are to be fitted directly onto implants or abutment level (compact conical), and intended for use as an aid in prosthetic rehabilitation.

Refer to individual product catalogues for product characteristics:
Internal Hex (M-Series CAT-2043 & PROVATA CAT-2060), Deep Conical (DC CAT-2042), Tri-Nex (CAT-2004), Internal Octagon (IT CAT-2005) and External Hex (CAT-2020).

*Figure 1*

| Code | | Implant to be used with | Cuff height | Retaining screw torque | Prosthetic screw options |
|---|---|---|---|---|---|
| Engaging | Non engaging | | | | |
| **External hex range** | | | | | |
| PKIP2H | PKIP2NH | ø3mm external hex implant | 2mm | 15Ncm | TS-P-16 (1.22mm hex) |
| PKBN2H | PKBN2NH | ø3.25mm external hex implant | 2mm | 15Ncm | 3 series Titanium screws. (Refer to Catalogues for codes & Instrument detail) |
| PKB2H | PKB2NH | ø4mm external hex & MAX-6 implant | 2mm | 20Ncm | |
| PKBA2H | PKBA2NH | ø5mm external hex & MAX-7 implant | 2mm | 20Ncm | |
| PKBBB2H | PKBBB2NH | ø6mm external hex & MAX-8 implant | 2mm | 20Ncm | |
| PKMAX9-2H | PKMAX9-2NH | ø9mm MAX-9 external hex implant | 2mm | 20Ncm | |
| **Tri-Nex range** | | | | | |
| PKC-EL-35-2 | PKC-NL-35-2 | ø3.5mm Tri-Nex implant | 2mm | 15Ncm | TS-L-18 (Unigrip) |
| PKC-EL-43-2 | PKC-NL-43-2 | ø4.3mm Tri-Nex implant | 2mm | 20Ncm | TS-L-20 |
| PKC-EL-50-2 | PKC-NL-50-2 | ø5mm Tri-Nex & TRIMAX7 implant | 2mm | 20Ncm | |
| PKC-EL-60-2 | PKC-NL-60-2 | ø6mm Tri-Nex & TRIMAX8 & 9 implant | 2mm | 20Ncm | |

| Code | | Implant to be used with | Cuff height | Retaining screw torque | Prosthetic screw options |
|---|---|---|---|---|---|
| Engaging | Non engaging | | | | |
| **DC- range** | | | | | |
| PKC-DC3-2 | PKC-NDC3-2 | ø3mm Deep conical implant | 2mm | 15Ncm | TS-DC3-14 (1.22mm hex) |
| PKC-DC4-2 | PKC-NDC4-2 | ø4mm Deep conical implant | 2mm | 20Ncm | TS-DC4-16 |
| PKC-DC5-2 | PKC-NDC5-2 | ø5mm Deep conical implant | 2mm | 20Ncm | TS-DC5-20 |
| Internal hex range | | | | | |
| PKC-M-2 | PKC-NM-2 | ø3.7 ,4.2, 5mm Internal hex implants | 2mm | 15Ncm | TS-Z-18 (1.27mm hex) |
| **Internal Octagon range** | | | | | |
| ITS-PKC1 | | ø4.8mm IT implants | 2mm | 15Ncm | TSIT2 (torx) |
| ITS6-PKC1 | | ø6.5mm IT implants | 2mm | 15Ncm | TSIT2 (torx) |
| **Abutment level (Compact Conical abutment)** | | | | | |
| | PKC-MC | ø4.8mm platform Compact conical abutments | 1mm | 15Ncm | 1 series Titanium screws. (Refer to Catalogues for codes & Instrument detail) |
| | PKC-MCW | ø6mm platform Compact conical abutments | 1mm | 15Ncm | |

**NOTE;** Refer to product catalogue for more information on Prosthetic screws and instruments.

## Indications:

Temporary Abutments engaging and non-engaging are indicated for screw retained restoration when the screw access hole is located through the cingulum of anterior teeth, and when the screw access hole is located through the occlusal surface of posterior teeth, both direct to an endosseous implant or on top of Compact Conical Abutments

PEEK temporary abutments are indicated for single unit, and PEEK temporary abutments non-engaging are indicated are indicated for multiple unit restorations.

## Contraindications:

Do not use in patients:
- who are medically unfit for dental implant procedures.
- who are allergic or have hypersensitivity to pure titanium or 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:

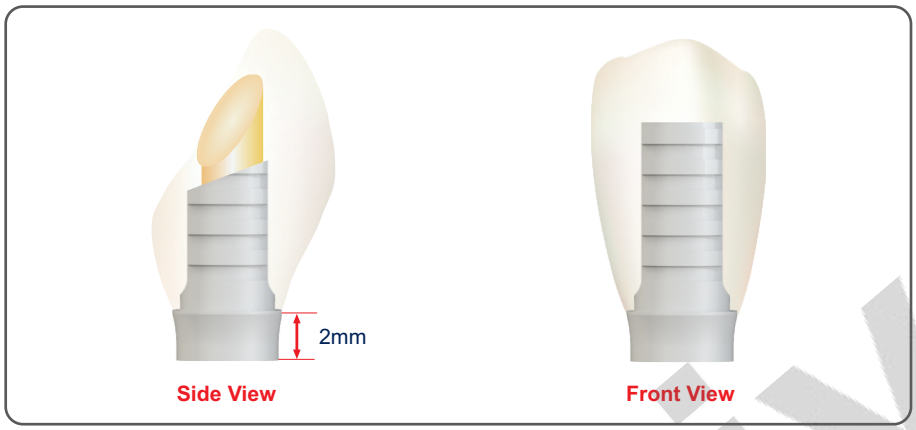
- New and experienced Implant users should do training before using a new system or attempt to do a new treatment method.
- Take special care when treating patients who have local or systemic factors that could affect the healing of the bone and soft tissue. (I.e. poor oral hygiene, uncontrolled diabetes, 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.
- Small diameter implants and are not recommended for use in the posterior region of the mouth
- 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
- 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.
- Regular patient follow-up, and proper oral hygiene is essential for favourable long-term results.

## Procedure for use:

### Chair side: (making a Temporary crown)

1. Connect the abutment to the implant and modify the abutment to the correct occlusal height, Modification of the abutment must be done with copious amounts of irrigation intra-orally. (Extra oral trimming of the abutment is the preferred recommendation).




2. Close the screw channel hole in a way that will ensure the retaining screw can be retrieved.
3. Make a temporary restoration by using a pre-formed stent and suitable temporary material.
4. Unscrew the temporary prosthesis, make final adjustments, to finish off the temporary crown.
5. Clean and disinfect the restoration as applicable per the restorative material manufacturer's instructions.
6. Attach the Temporary abutment to the endosseos implant or on compact conical level:
   a. For a single unit: Place and tighten the retaining screw. Verify the correct seating of the restoration using radiographic imaging. Tighten the restoration using a torque wrench, to the torque value specified for the applicable prosthetic screw. (Refer to Figure 1)
   b. For multiple units: Place and tighten the retaining screw. Verify the correct seating of the restoration using radiographic imaging. Tighten the restoration using a torque wrench, to the torque value specified for the applicable prosthetic screw.(Refer to Figure 1)
   c. For Compact conical abutment multiple units: Place and tighten the retaining screw. Verify the correct seating of the restoration using radiographic imaging. Tighten the restoration using a torque wrench to 10-15Ncm.
7. Close screw access hole.
8. Cement final prosthesis if applicable.

## Laboratory procedures:

1. The laboratory receives the impression either implant level or abutment level.
2. The corresponding laboratory analogue is connected to the impression coping, fabricate a working model with removable gingival mask or soft tissue material.
3. Follow the same steps to manufacture a temporary crown. Deliver the crown for placement in the mouth.

## Materials:

PEEK polyetheretherketone

Abutment screws: Titanium alloy Ti-90%, Al-6%, V-4%

## Magnetic Resonance (MR) safety information:

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.

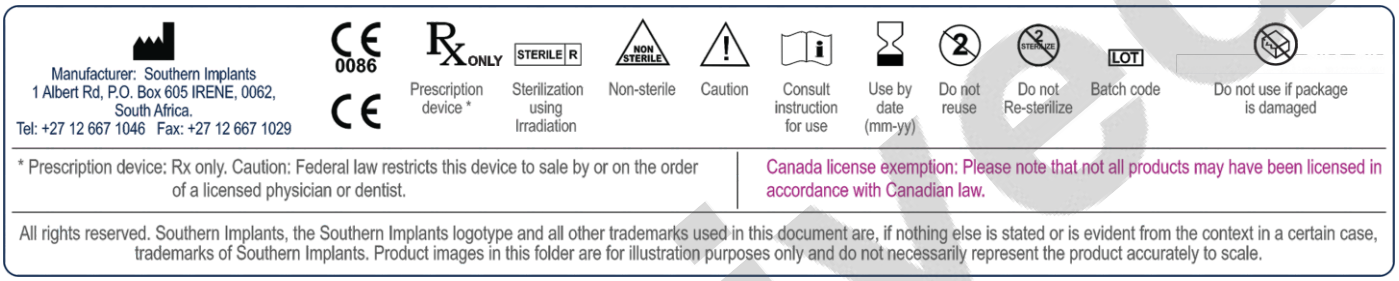
## Storage, Cleaning & Sterilization

These abutments are supplied sterile 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. Do not re-sterilize or autoclave these components. The product must be stored in a dry place in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics.

## Disposal:

Disposal of the device and its packaging shall follow local regulations and environmental requirements, taking different contamination levels into account.

## Symbols & Warnings






For Technical Assistance or additional product literature, please contact Southern Implants.

**Manufacturer and head office:**
**Southern Implants (Pty) Ltd**
1 Albert Road
P O Box 605
Irene
0062
**South Africa**

**Tel:** +27 12 667 1046
**email:** info@southernimplants.com

**European Representative**
**Southern Implants (Pty) Ltd**
Building 3, Chiswick Park
566 Chiswick High Road
Chiswick
London W4 5YA
**United Kingdom**

**Tel:** +44 20 8899 6845 / 6 / 7
**email:** info@southernimplants.co.uk

**Americas**
**Southern Implants North America**
225 Chimney Corner Lane
Suite 3011
Jupiter
Florida 33458
**USA**

**Tel:** +1 561 472 0990
**email:** customercare@southernimplants.com

## 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.