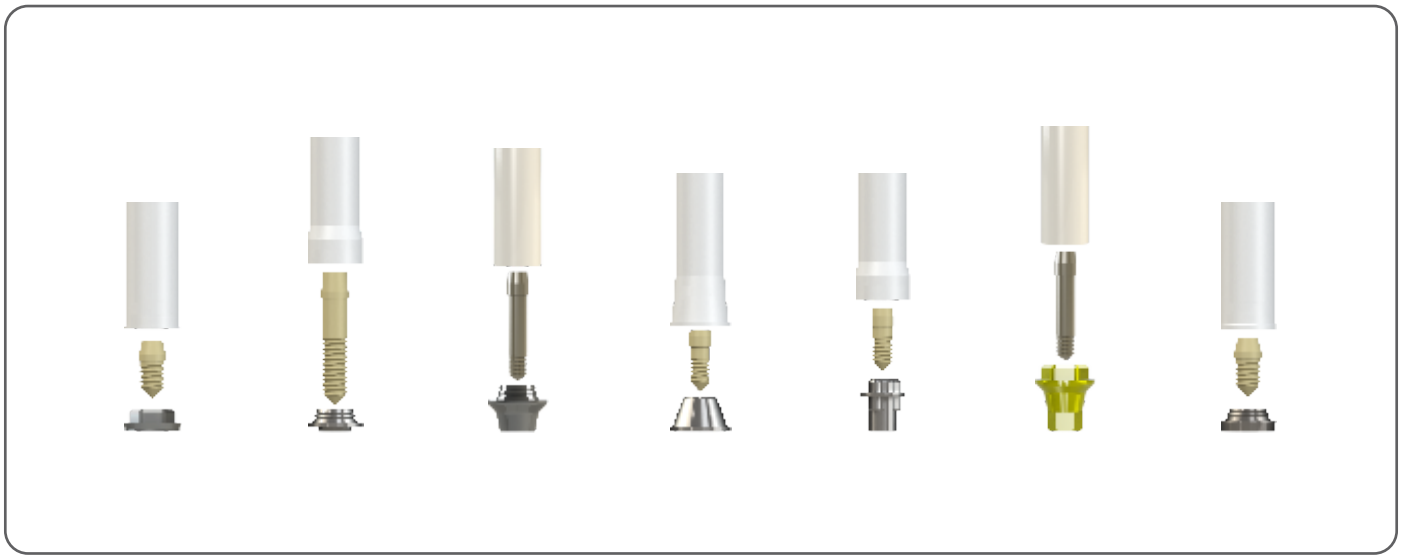
SOUTHERNIMPLANTS

INSTRUCTIONS FOR USE:
Passive Abutments



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.

Description:

These are pre-manufactured abutments for use as an aid in prosthetic rehabilitation. The passive abutment can be connected direct to an endosseous implant, or connect the prosthesis to a compact conical abutment. The Passive Abutment consist of a metal 'cylinder, a Plastic burn-out sleeve and a PEEK luting screw.
The Passive Abutments are available in the Internal Hex, Deep Conical, Tri-Nex, IT, External Hex and Compact Conical connection interfaces. Refer to individual product catalogues for product characteristics: M-Series (CAT-2043), DC (CAT-2042), Tri-Nex (CAT-2004), Provata (CAT-2060), IT (CAT-2005), External Hex (CAT-2020).

Indications:

Engaging Passive Abutments are indicated to achieve a passive fit on a single tooth restoration direct to an endosseous implant.
Non-engaging Passive Abutments are indicated to achieve a passive fit for multiple unit restorations on endosseous implants and on top of Compact Conical abutments.

Contraindications:

Do not use in patients:
- who are medically unfit for dental implant procedures.
- who are allergic or have hypersensitivity to pure titanium or titanium alloy (Ti-6AL-4V)
- 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:

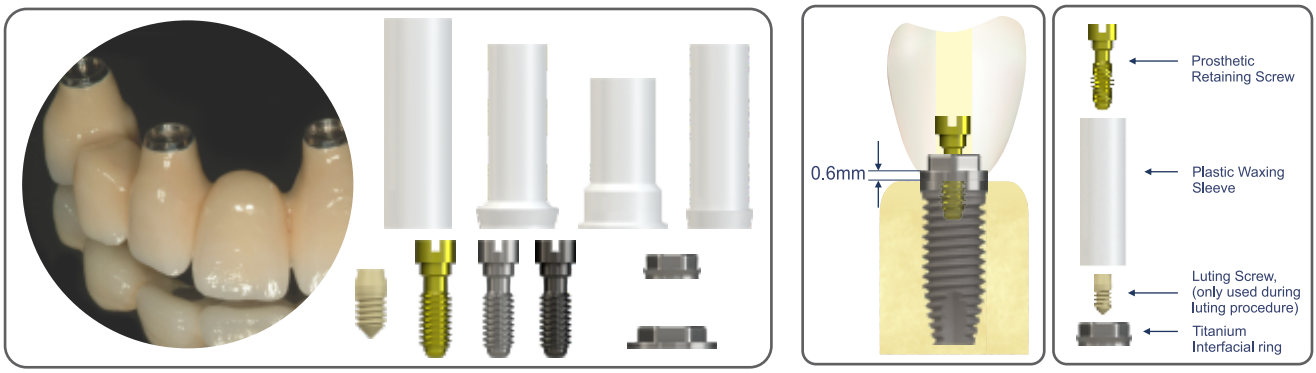
- New and experienced Implant users should do training before using a new system or attempt to do a new treatment method.
- Take special care when treating patients who have local or systemic factors that could affect the healing of the bone and soft tissue. (I.e. poor oral hygiene, uncontrolled diabetes, 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 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 must be achieved are essential for favourable long-term results.

The Concept:

The Passive Abutment concept allows one to achieve predictable passive fit of cast structures in a practical and repeatable way and thus eliminates the need for complex and intensive laboratory procedures usually undertaken to improve the fit e.g. sectioning and soldering of frameworks. Passive fit is achieved by luting a pre-machined titanium interface component into the finished prosthesis, using the laboratory master model as the blueprint for fit. No additional clinical steps are required.



Detailed Description:

The Passive Abutment consists of four components:

1. Plastic cylinder - this component is incorporated into the wax-up of the structure and thus becomes part of the casting. This burn-out component is not used clinically.
2. Titanium interfacial component/abutment - this pre-machined component forms the final interface between the casting and the implant.
3. Luting screw - this small screw is used to clamp the interfacial component onto the laboratory analogue during the process of luting the casting onto the interfacial component. The component is not used clinically.
4. Prosthetic screw - this screw retains the completed prosthesis to the implant at final placement and provides a compressive force across the cement line. The screw is included in the package for DC range.

Overview of Use:

The plastic cylinder is incorporated into the wax-up and becomes part of the cast structure. The casting may then undergo further laboratory processing e.g. ceramic firing, finishing and polishing before being assembled with the interfacial component. The titanium interfacial component is kept separate from the manufacturing of the casting and is therefore not subjected to degradation by heat-cycles or de-vesting and finishing procedures (as in the case of a cast-to gold cylinder). The integrity of the machined part is therefore maintained in original condition.
The finished cast structure is assembled with the interfacial ring by luting on the laboratory model, before placement in the patient's mouth. For assembly, the titanium interfacial component is clamped to the analogue on the master model by means of the luting screw. The luting screw ensures that the interfacial component is held in full contact with the analogue.
The finished prosthesis is then luted to the clamped interfacial ring using a resin cement. In this way the resin cement serves as a space filler between the casting and the interfacial ring, thus compensating for any minor casting and finishing discrepancies, so eliminating misfit of the casting to the implant. At placement in the mouth, the prosthetic screw retains the prosthesis to the implant and maintains a compressive force over the cement line. The cement line is therefore not responsible for retention of the prosthesis, but is merely a space filler. The luting screw is discarded after the luting procedure.

The Application:

The Passive Abutment is intended for use in fabrication of implant-supported SCREW-RETAINED CASTINGS (e.g. crowns, bridges, mezo-structures, cast bars, custom posts) on one or more implants where excellent prosthetic fit is desired. The use of a burnout plastic cylinder allows freedom of choice in choosing the casting alloy. The complexity of laboratory procedures is greatly reduced when compared to complex castings incorporating gold cylinders.

For direct connection to all implants, both non-engaging and engaging versions are available:

1. Non-engaging versions are indicated for multi-implant cases. The non-hexed (non-engaging) interfacial component has an internal taper fit to allow for non-

parallelism of implants.
2. Engaging versions are indicated for single implant cases and multi-unit custom abutment cases.

Problems of Conventional Cast Structures:

Frameworks incorporating cast-to gold cylinders are very commonly used in implant reconstruction, as are castings fabricated using plastic burnout cylinders. These castings, however, are subject to significant difficulties as follows:

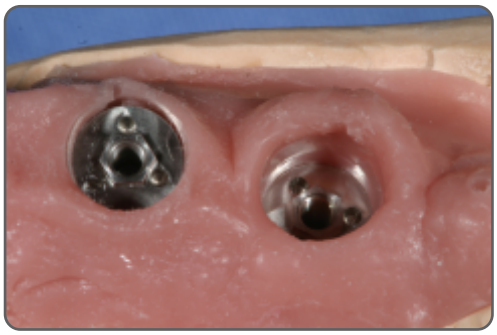
1. **Significant deterioration of the fitting surface of the cast structure** occurs as a result of laboratory procedures i.e.
   - Sandblasting of the casting to remove investment material will degrade the fitting surface and therefore degrade the inter-implant passivity of fit.
   - The casting is subjected to repeated high temperature cycles during casting and porcelain firing procedures. This results in oxidation of the fitting surfaces and further deterioration of fit.
   - The gold fitting surface is deteriorated by multiple "fittings" on the model, especially if the analogues are not kept clean.

The larger and more complex the casting, the greater the likely degree of discrepancy of fit. Hence, larger castings with fit discrepancies are often cut and soldered, or laser-welded. It is commonly reported that these attempts to improve the fit result in even greater fitting problems and this may be amplified by porcelain firing.

2. **Clinical implications of mis-fitting implant structures**:
   Discrepancies in fit are extremely difficult to detect clinically, if not impossible where the interface is subgingival. Vertical misfits will only be detected on x-ray if the misfit occurs interproximally and the x-ray beam is oriented perpendicular to the interface. If the discrepancy is in the bucco-lingual plane, it will not be detected on x-ray. Even gross discrepancies may be missed where x-ray techniques are not optimal.

Most importantly, poorly fitting prostheses can result in:
- bacterial accumulation at the prosthetic/implant interface
- mechanical strain being applied to the implant, which may result in bone loss
- poor preload of retaining screws and thus more frequent screw loosening
- fatigue loading of the retaining screws, culminating in screw fracture

The Laboratory Procedure

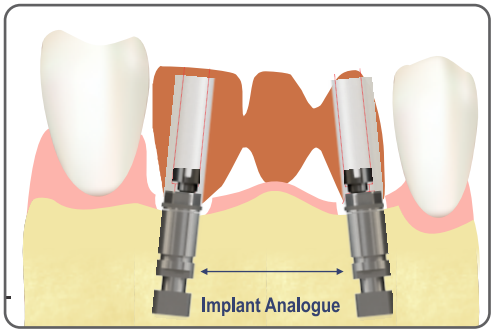


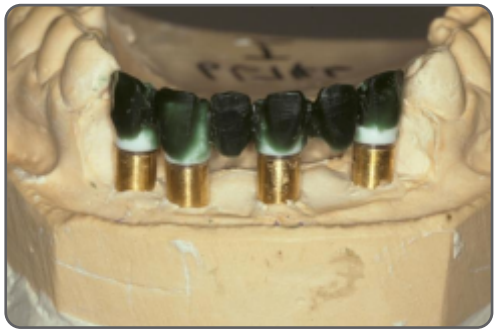
1. Model preparation:

The appropriate analogues must be selected and the model prepared using a silicon or rubber soft tissue mask. The highly recommended use of a removable soft tissue mask will allow easy access to the analogues for further lab procedures and will greatly ease later assembly procedures.

2. Wax-up:

The Titanium Ring and Waxing Sleeve are assembled on each implant analogue, using the laboratory equivalent of the prosthetic screw (laboratory screw) to hold them in place. Do not over tighten, so as to avoid distortion of the plastic. The waxing sleeve can be cut back or added to, as needed. The wax-up is completed and sprued before removing the wax-up from the model.



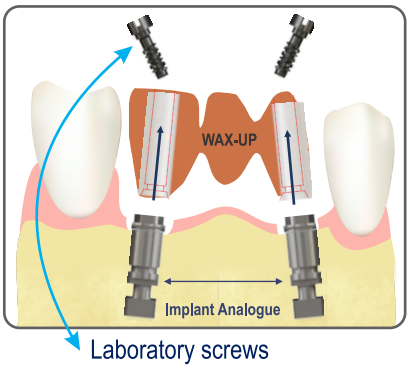


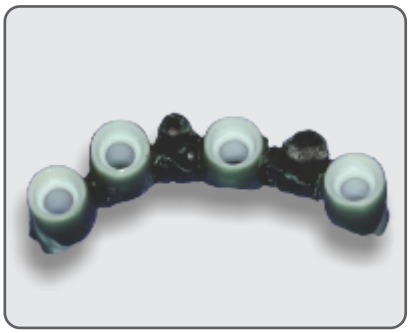
3. Investing and Casting:

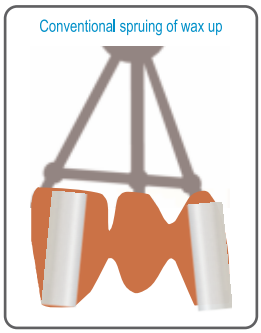
The retaining screw must be removed to allow the wax-up with plastic cylinders to be lifted from the model, leaving behind the loose titanium interfacial component.
Standard procedures are used for investing and casting. An appropriate casting alloy must be chosen, depending on whether a ceramic veneered 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.

For complete burn-out: The plastic cylinder requires an oven temperature of 820°C for at least 45 minutes.

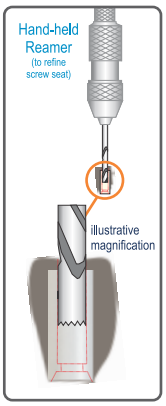
As with all implant work, it is best to devest ultrasonically as opposed to blasting with sand or glass beads. This helps preserve the sharp edges and fitting surfaces of the casting.







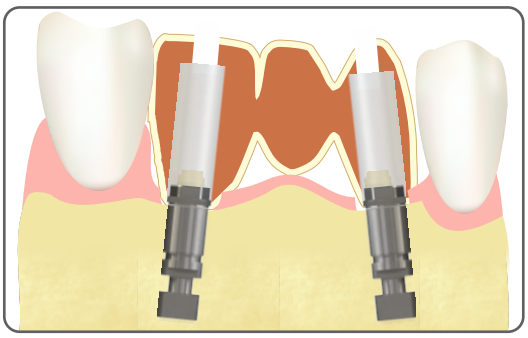
4. Refining the screw seat:



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. (LT18-2.4, LT18-2.6 or LT18-2.8) The correct diameter of reamer must be chosen. This is an important step to ensure proper seating and tightening of the prosthetic screw.

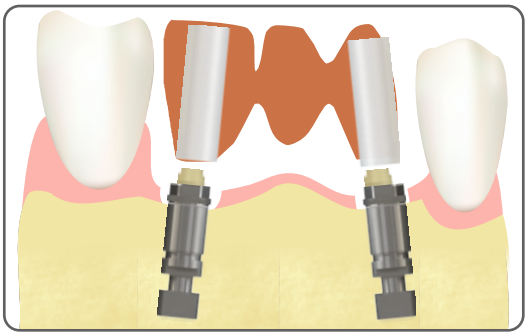
5. Fitting the casting to the model:

Casting fits over luting screws & interfacial rings



The titanium interfacial components are secured to the analogues using the small luting screws. Do not over tighten, as this may result in the head of the Peek luting screw breaking off. The casting is placed over the secured interfacial components. The casting can be easily fitted and removed from the model without the need to remove and replace the luting screws.
If the prosthesis needs to be screw-retained on the model, then one or more of the small luting screws can be exchanged for a prosthetic screw (the prosthetic screw secures the prosthesis to the analogue, while the short luting screw has a smaller head and can only retain the titanium interfacial component to the analogue.)

Luting screws secure interfacial rings to analogues.



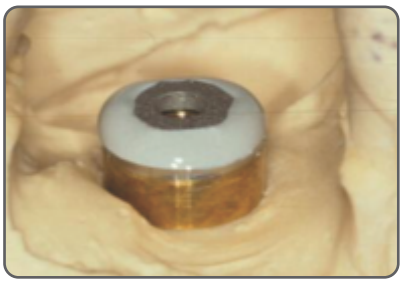
The peek screw has a 1.22mm hex broached deep into the screw. This helps to remove the screw in the event that cement locks the screw in position.

6. Luting the prosthesis to the titanium interfacial component:

After completing the fabrication of the prosthesis, sandblast the fitting surface of the casting. It is not necessary to sandblast the top surface of the Titanium ring. Under all circumstances, avoid sandblasting the polished collar of the titanium ring.

After sandblasting, it is very important to disassemble and ultrasonically clean the following:
- the titanium interfacial components
- the short luting screws
- the fitting surfaces of the prosthesis

Also clean the analogues (Implant Replicas) in the model by brushing with soap and water or steam cleaning to remove any debris which may interfere with perfect seating of the interfacial components.



Luting of the prosthesis to the titanium rings is to take place on the master model.
- attach the titanium rings to the model with the short luting screws.
- apply a self cure resin cement or dual cure resin cement (e.g. Unicem by 3M) to the sandblasted surface of all of the titanium rings.

(NB refrigeration of self-cure resin cements will usually lengthen working time for ease of use on multi-unit structures).

In the event that cement locks the luting screw in position, a diameter 1.5mm round burr is rotated into the hex of the screw. This usually separates the screw head from the shaft and frees the prosthesis. Take care not to damage the components. The prosthesis can then be removed.

IMPORTANT: Limit the amount of resin cement being applied to the angle between the sandblasted horizontal plane and vertical plane of the titanium ring. This will avoid excess cement extruding upwards through the screw hole in the casting and so inadvertently locking the luting screw into the cement. Definitely avoid placing any cement in the area immediately around the head of the luting screw.
Fit the prosthesis over the titanium rings and settle the prosthesis firmly into place with finger pressure to extrude excess cement. Arch castings can be left seated under their own weight to allow cement to harden. Smaller bridges or single units need to be held lightly in place by using one or more prosthetic screw in place of a chosen luting screw, to allow cement to harden. (E.g. use the middle screw in a three-unit structure).

VERY IMPORTANT: do not over tighten the prosthetic screw being used to retain the prosthesis during cement hardening as this may result in distortion of a multi-unit structure.

Fig. 1

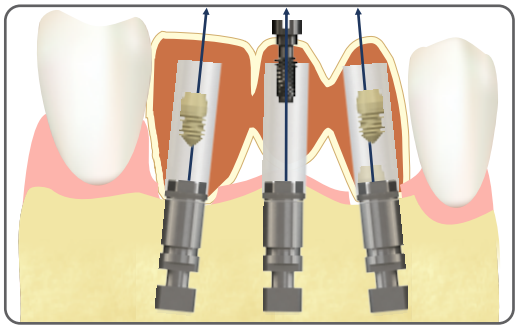


Fig. 2

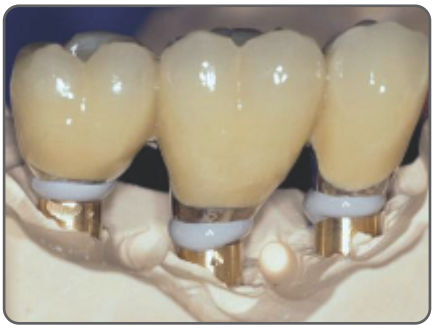
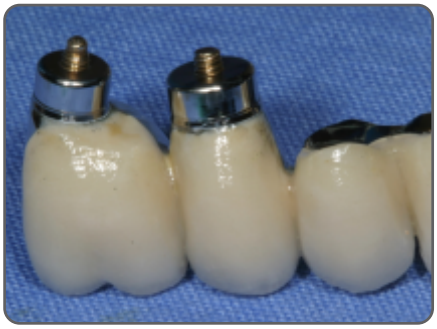


Fig. 3



Finishing & Polishing:

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. Remove excess extruded resin cement (fig. 2) using a sharp blade, probe or hand scaler. (Extruded cement breaks away easily in large pieces from the outer polished surfaces of the structure and titanium ring).
Attach polishing protectors of correct diameter to each of the fitting surfaces of the cemented titanium rings (fig. 3). Polish the remaining cement line using a fine edged, lens shaped rubber wheel and blend the casting into the titanium ring where needed. You will notice that the cement line is often not of constant thickness. This variation is indicative of the extent of casting misfit which existed and has now been corrected by the cement space of the Passive Abutment.
Once polishing is completed, remove protector caps and replace the casting on the cleaned model analogues to inspect and verify the quality of fit obtained. (Resin cement is best cleaned from analogues using a brush with alcohol) The fit would be expected to be excellent in all areas, but, in the unlikely event that a luting error has occurred, the offending titanium ring may be removed, cleaned and re-cemented to the prosthesis as required. A titanium ring can easily be removed by forcing a sharp blade into the cement line, or by punching out the ring using the shaft of a lab handpiece drill applied through the screw access hole (place the bridge rings down on a folded towel for padding and give the drill shaft a sharp tap).

VERY IMPORTANT: as this technique relies absolutely on the accuracy of the master model to achieve passive fit of the prosthesis, it is vital that accurate impression techniques be used and that the quality and condition of the model and analogues be maintained at all times.

Repairs:

If one needs to put a ceramo-metal Passive case back into the furnace for repair, a gradual heating cycle is used to drive out moisture from the ceramic (usually 600ºC for 6-8 hrs). During this heating phase, the cement will be degraded, allowing the rings to be easily removed from the structure. (A higher temperature of 800ºC will burn out the cement, if required). This is a convenient advantage of the system, as the rings can be recovered for re-use. If the user feels that the condition of the rings is not ideal, one may decide to use new rings for the re-cementation. It is an advantage of the Passive system that the fitting surfaces can be removed from the casting to avoid damage by heat cycles during the repair process and then be refitted. (It is essential to always keep the master model)

Clinical procedures:

1. Clean and disinfect the restoration as applicable per the restorative material manufacturer's instructions.
2. For a single unit: Place the unit, 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. (External hex range, Tri-Nex range, IT range, M-Series range, Provata range – 32-45Ncm for Final prosthetic screw) (DC-range, ø3mm to 15Ncm, ø4mm to 20Ncm, ø5mm to 32Ncm)
   For multiple units: Place the multi-unit structure, 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. (External hex range, Tri-Nex range, IT range, M-Series range, Provata range – 32-45Ncm for Final prosthetic screw) (DC-range, ø3mm to 15Ncm, ø4mm to 20Ncm, ø5mm to 32Ncm)
   For Compact conical abutment multiple units: Place the multi-unit structure on top of the compact conical abutments. Verify the correct seating of the restoration using radiographic imaging if applicable. Tighten the restoration using a torque wrench, to 10-15Ncm)
3. Close screw access hole.
4. Cement final prosthesis if applicable.

Materials:

Passive Abutment:	Titanium grade,2,3,4 or 5
Plastic Sleeve:	Polyoxymethylene (POM)
Luting screw:	Medical grade PEEK (DES-3000)
Abutment screws:	Titanium alloy Ti-90%, Al-6%, V-4% or Gold Alloy Au-61%, Ag-16.5%, Pt-13.5%, Cu -9%

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 delivered non-sterile and for single use. Final restoration should be cleaned and disinfected, as per restorative material manufacturer's instructions, before intra oral use.
Pre-vacuum sterilization method: Steam sterilise the abutments at 132°C (274-279°F) at 180-220kPa for 3-7 minutes. Dry for at least 20 minutes in the chamber. Only a FDA approved wrap or pouch for steam sterilization must be used.
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.

Symbols & Warnings

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

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