SOUTHERNIMPLANTS

INSTRUCTIONS FOR USE:
Gold 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 dental abutments that can either be connected direct to an endosseous implant, or connect the prosthesis to a compact conical abutment for use as an aid in prosthetic rehabilitation. The Gold abutment includes a Plastic burn-out sleeve to aid in the laboratory procedure during wax-up procedures.
Refer to specific Implant catalogue for product characteristics:
M-Series (CAT-2043), DC-Range (CAT-2042), TRI-NEX-range (CAT-2004), Provata-Range (CAT-2060), IT-Range (CAT-2005), External Hex- Range (CAT-2020)

Indications:

Gold abutments engaging & non engaging are indicated to be connected direct to an endosseous implant for single or multiple restorations.
Gold abutments engaging, are indicated for single unit crowns where this component is used to create a custom abutment that is screw retianed to the implant with a cement retained crown. When the screw access hole is located through the cingulum of anterior teeth or the occlusal surface of posterior teeth the custom abutment can be directly veneered and attached to the implant. Non-engaging gold abutments are indicated for multiple screw retained prosthesis. When the screw access holes are located through the cingulum of the anterior teeth and the occlusal surface of posterior teeth, the custom abutments can be directly veneered and attached to the implants. This is indicated for implants with less than 40° divergenge to allow path of insertion.
If the position of the screw access holes are not favourable, custom abutments or a structure can be fabricated and retained to the endosseous implants with a cemented restoration.

Contraindications:

Do not use in patients:
- Who are are medically unfit for dental implant procedures
- Who are allergic or have hypersensitivity to pure titanium or titanium alloy (Ti-6AL-4V), gold, palladium, platinum, iridium.
- Where adequate numbers of implants could not be placed to achieve full functional support for 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.

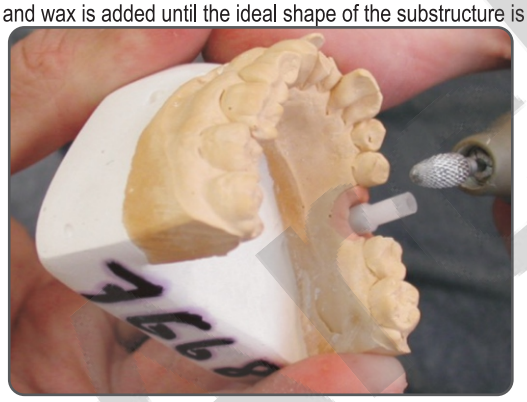
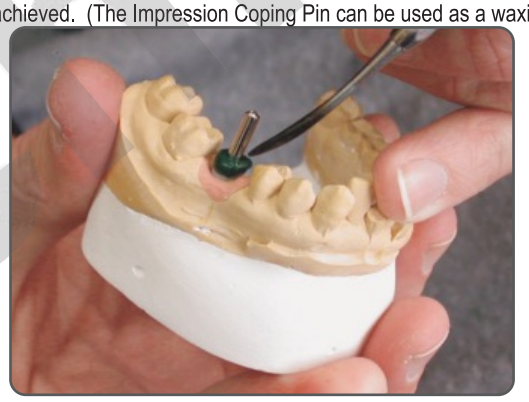
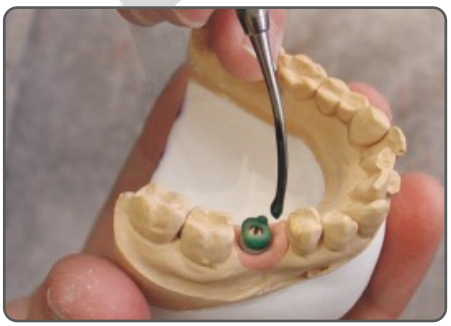
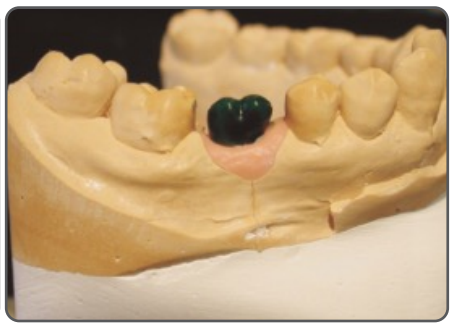
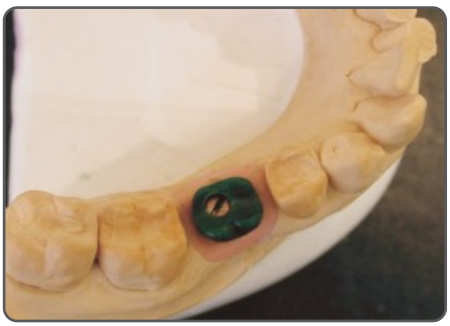
Clinical procedure:

1. Connect the impression coping/s to the dental implant/s (or compact conical abutments if applicable).
2. Take an open or closed tray impression. When closed tray procedure is used, transfer the copings to the impression.
3. Connect the healing abutment or temporary restoration direct to the dental implant/s (or compact conical abutments if applicable).

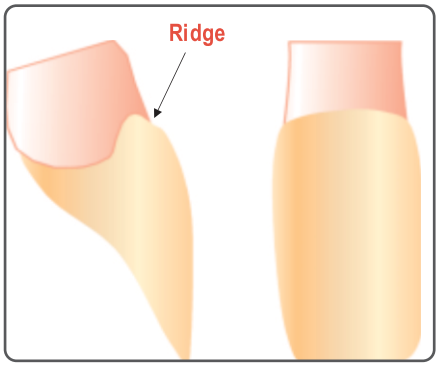
Laboratory procedures:

This abutment has a machined gold base, together with a plastic waxing sleeve. The plastic sleeve aids in the wax up process.

1. Prepare the master model and obtain the correct size Gold abutment with laboratory screw.
2. The Gold abutment is screwed onto the model. Trim the plastic sleeve to the correct occlusal height. The Plastic Sleeve is then reduced out of occlusion and wax is added until the ideal shape of the substructure is achieved. (The Impression Coping Pin can be used as a waxing sleeve.)

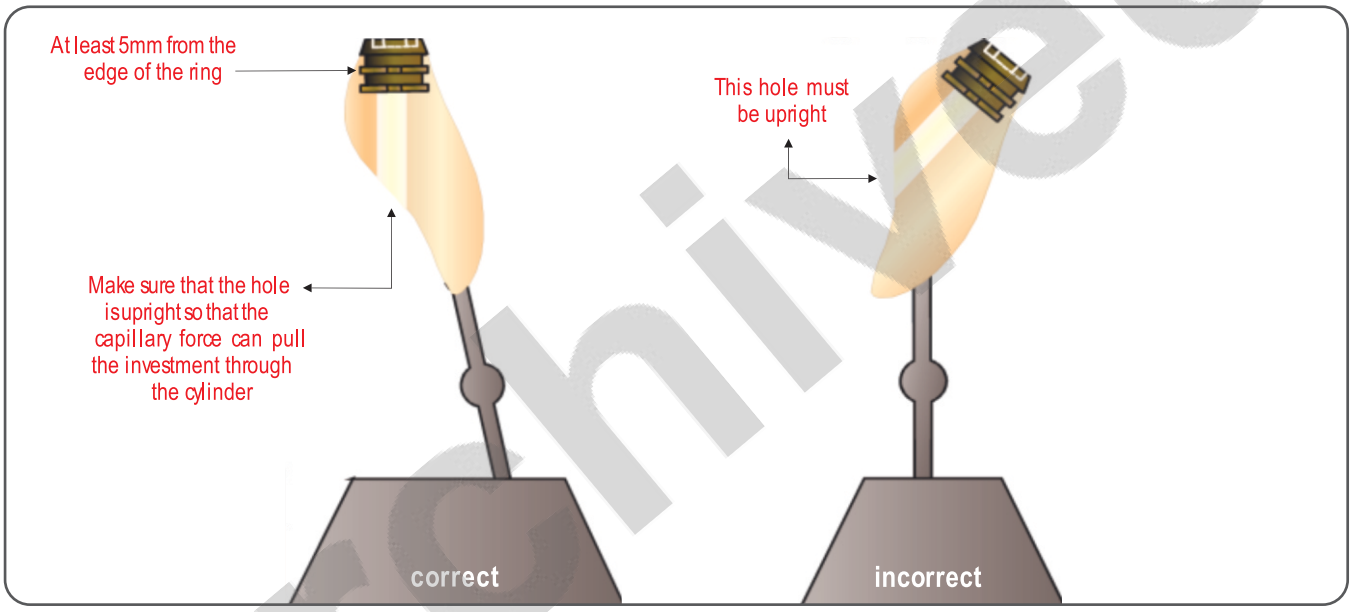






NOTE: The technician can determine the place where the soft tissue will settle against the tooth by making a slight ridge as shown on the left. This must be done to match the adjacent teeth.



NOTE: The shape of teeth is seldom "round". The shape of the root of the tooth must be developed sub-gingival so that where it emerges through the tissue it is the right shape and there must be no ridge-lap. This is referred to as the "emergence profile".

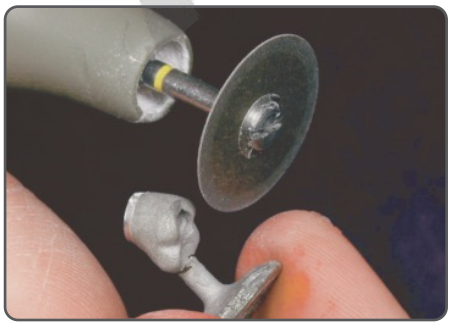
4. Add the sprue to the UCLA abutment with its wax and then invest it.



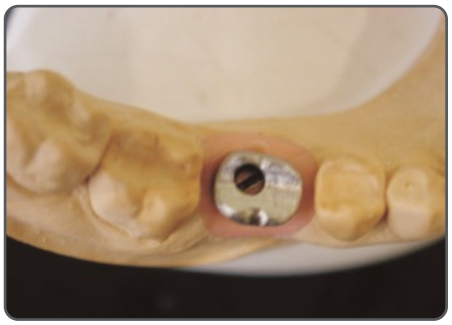
5. Burn out the wax and plastic by placing the model into the furnace according to the investment manufacturer's specifications and leave at final temperature for at least one hour. The plastic sleeve requires more time to burn out than does wax. It is advisable not to leave these rings at low burnout temperatures, i.e. 400° to 500°C, as this is the optimum temperature for investment to expand. Too much expansion on an implant case could result in a metal creep on the gold cylinder.

6. After casting, the removal of the investment material is most critical. IT MUST BE REMOVED ULTRASONICALLY. DO NOT sandblast or blast with glass beads, the fitting surface which must fit on the implant. If this surface is blasted in any way, the precision-machined gold part will not fit the implant as intended!

7. Work off the coping as normal. Take care not to damage the fitting surface.

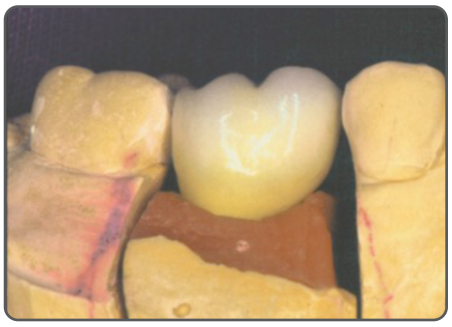


8. After de-oxidising and opaqueing, the porcelain (or composite) can now be added. NOTE: It is not only important to get the shade match correct, but also the surface texture of the crown. Replicate the surface texture of the adjacent tooth as much as possible and a slight shade mismatch will probably not be noticeable.



9. At the screw access hole, a porcelain margin must be built up. This will enable the dentist to do a composite closure of the screw access hole without an unsightly grey metal ring showing.

10. Before sending the crown and model to the dentist, clean the model thoroughly with soap, water, and a toothbrush, or steam clean. Then clean the abutment crown and its screw, preferably in the Ultrasonic bath. Assemble the crown to the model and send it to the dentist.



Occlusion:
Implant borne crowns are usually kept out of occlusion by about one-tenth of a millimetre to avoid complications.

Clinical procedures:

1. Clean and disinfect the restoration as applicable per the restorative material manufacturer's instructions.
   a. For a single unit: Place and tighten the restoration 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. (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)
   b. For multiple units: Place and tighten the restoration 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. (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)
   c. For Compact conical abutment multiple units: Place and tighten the restoration 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. (External hex range, Tri-Nex range, IT range, M-Series range, Provata range and DC-range to 10-15Ncm)
2. Close screw access hole.
3. Cement final prosthesis if applicable.

Gold abutment casting specifications:

The Gold abutments are not made of porcelain-bonding alloy. The alloy is designed to have oxidation during casting-on procedures. Some labs do bond porcelain directly onto gold abutments. This could result in the porcelain turning slightly green or chipping off due to a poor bond. The melting temperature of the gold alloy is approx. 1475°C. Labs cast on at +/-920°C – no higher. As this could result in the edges of the cylinders distorting. The furnace should run up straight to the casting temperature (reduces investment expansion. Too much expansion could result in overflow of metal onto the fitting surface of the abutments.)
The Co-efficient of Expansion are:
25-500°C - 11.9
25-600°C - 12.2

Cautions:

Casting temperature: At 650°C there is a high chance of a miscast. Usual casting temperature is 900°C. A Phosphate bonded investment must be used.
When investing, avoid the use of a tension reliever as it leaves a residue, which can result in metal creep.
Once the cast metal has been oxidized, it needs to be sandblasted before applying opaque the seating surface of the gold cylinder should be blocked out with a thin layer of wax to avoid any damage during blasting procedures. An alternative is to protect this surface by attaching a polishing protector cap.

Recommended casting alloys:

Commonly used metals which are used for custom posts (non-ceramic bonding):

- Contact your restorative material supplier for a compatible material to Southern Implants gold abutments. Some of them are: Stabilor, Procast Y45-Argen, Argeno 1.

Ceramic bonding alloys:

- Contact your restorative material supplier for a compatible material to Southern Implants gold abutments. Some of them are: Argeno 1, Degudent U, Argident 3, Degunorm – Gold gate system, Bond-on 4, and Degudent G.

Materials:

The Material of the Gold abutment is Ceramicor which is alloyed in Switzerland.

Chemical composition:

Gold Abutment: Gold alloy: Au-60%, Pt-19%, Ir-1%
Plastic Sleeve: Acetal
Abutment screws: Titanium or Gold Alloy

Magnetic Resonance (MR) safety information:

The Gold abutment 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 the Gold abutment in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Storage, Cleaning & Sterilization:

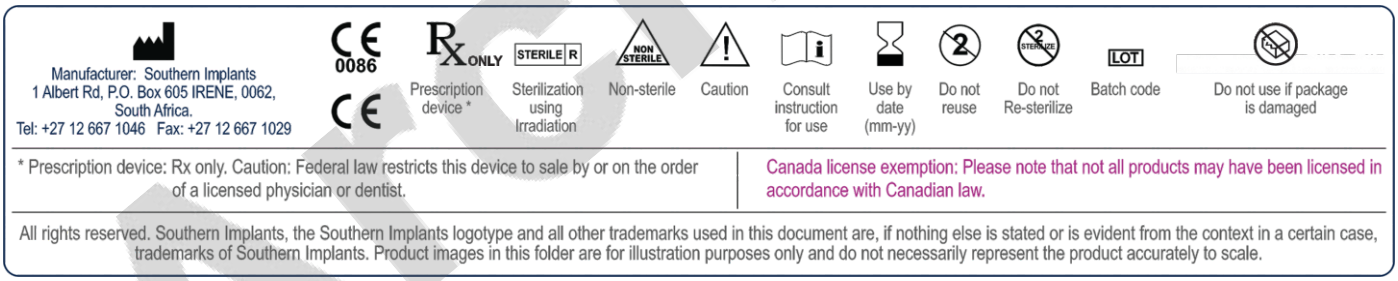
These abutments are delivered non-sterile for single use. Final restoration should be cleaned and disinfected, as per restorative material manufacturer's instructions, before intra oral use.
Pre-vacuum sterilization method: Steam sterilize the abutments at 132°C (270°F) at 180-220kPA for 3-7minutes. Dry for at least 20 minutes in the chamber. 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

CAUTION: (USA ONLY)
United States Federal Law restricts this device to sale to, or on the order of, a licensed dentist or physician.



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

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