SOUTHERNIMPLANTS®
Innovative Treatment Solutions

INSTRUCTIONS FOR USE: DENTAL IMPLANT PRODUCTS

This document applies to the Southern Implant line of dental implants, abutments and associated surgical, restorative and dental laboratory components.

All Southern Implants' products are intended to be used by appropriately trained and licensed professionals.

For detailed information on a specific product and procedure, please refer to the individual product catalogue, packaging labels and/or the appropriate manual.

INDICATIONS

Southern Implants dental implants are intended to be implanted in the upper and lower jaw arches to provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses or full arch prostheses. It further adds the option for immediate placement, and function on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.

DESCRIPTION

Southern Implants manufactures dental implants from biocompatible titanium and restorative components from titanium, titanium alloy, gold alloy and specific biocompatible polymers. The "cast-to" abutments are made from biocompatible gold or cobalt chrome alloy so that dental technicians can cast precious and semi-precious metals onto these components. The ceramic abutments are made from biocompatible zirconia.

For specific product descriptions refer to individual product packaging labels.

CONTRAINDICATIONS

Contraindications include: (1) cases where the remaining jaw bone is too diminished to allow implant installation, (2) patients allergic to metallic implants, (3) patients with insufficient mental health precluding patient cooperation, (4) patients who abuse drugs or alcohol, (5) patients who have conditions such as but not limited to myocardial infarct within the last year, oral infections, or malignancies, (6) patients who have uncontrolled diabetes or blood disorders.

WARNINGS

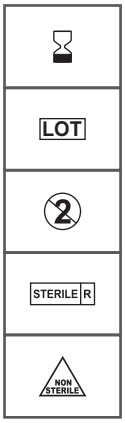
For the safe and effective use of dental implants, it is strongly suggested that specialised training be undertaken, including hands-on training to learn proper technique, biomechanical requirements and radiographic evaluations. ***THESE INSTRUCTIONS ARE NOT INTENDED AS A SUBSTITUTE FOR ADEQUATE TRAINING***. 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 and/or loss of supporting bone. Southern Implants will not accept liability for damage caused by improper implant treatment.

Southern Implants dental products have only been validated for use with the corresponding Southern Implants abutments and accessories. Although care has been taken to create interfaces that are common to the industry, Southern Implants cannot guarantee outcomes obtained using components from other manufacturers. Please refer to individual product catalogues for interface requirements. Southern Implants will not accept liability for damage caused by improper selection of incompatible abutments and accessories.

LABELLING SYMBOLS

The following symbols are used on the packaging labels:

1) "USE BY"
2) "BATCH CODE"
3) "DO NOT REUSE"
4) "STERILIZED USING IRRADIATION"
5) "NON-STERILE"



6) "CONSULT INSTRUCTIONS FOR USE"

7) "CAUTION"

8) "DO NOT RESTERILIZE"

9) "STERILE UNLESS PACKAGE IS OPENED OR DAMAGED"

10) CE MARK (if applicable)

11) Caution: (USA Only) US Federal Law restricts this device to sell to, or on the order of a licensed dentist or physician.

PACKAGING

1) Implants: The outer package consists of a rigid, clear box which acts as protection for the inner package. The inner package consists of a clear plastic-formed bubble-type base with a "peel-back" lid. The contents of this inner package are sterilized by gamma irradiation. Labelling information is located on the surface of the peel-back lid and on the outside of the rigid box. Within the inner package there is a hollow tube which contains one implant. Sterility is assured unless the inner package or it's seal is damaged or opened.
2) Sterile components are packed in a peel pouch or bubble-type base with a "peel-back" lid and sterilised by gamma irradiation. 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.
3) Non-sterile components are supplied clean but not sterile in a peel pouch or bubble-type base with peel-back lid. Labelling information is located on the bottom half of the pouch, or on the surface of the peel-back lid.

STERILITY

All dental implants and some 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. Products provided non-sterile must be cleaned and sterilized according to the directions in the Surgical Manual, prior to use.

SURGICAL AND PROSTHETIC PROCEDURES

For detailed information of the surgical and prosthetic procedures refer to the SURGICAL (CAT-2004, CAT-2005, CAT-2020, CAT-2042, CAT-2043, CAT-2052) and PROSTHETIC MANUALS (CAT-2001).

CLEANING

- Please Refer to CAT-1039
- Used instruments should be soaked immediately in instrument cleaning solution to avoid the drying of blood, saliva and tissue residue.
- Used surgical trays including grommets must be cleaned with suitable disinfectants.
- Multiple-part instruments must be disassembled prior to cleaning and sterilization.
- Internal debris/residue of instruments must be removed with a soft brush.
- Instruments should be inspected, cleaned separately and discarded if damaged.
- Best results are achieved if surgical instruments are segregated and cleaned by material type.
- Instruments and trays are to be cleaned and disinfected in a dedicated instrument washer (or alternatively by hand, followed by an ultrasonic bath with a detergent appropriate for surgical instruments).
- Instruments and trays must be rinsed immediately after use.
- Instruments and trays should not be left wet for extended periods of time.

STERILIZATION

- Please Refer to CAT-1039
- Caution: It is the responsibility of the user to establish whether the sterilizer has been cleared by the FDA or the country's applicable authority, to meet these recommended parameters, and to use accessories (BIs, CIs, and wraps/pouches/containers) cleared by FDA (or the country's applicable authority) and labeled for use with the given parameters.
- Pre-Vacuum method: Steam sterilise the abutments at 134-137°C (274-279°F) at 180-220kPa for 3-7 minutes. Dry for at least 10 minutes in the chamber. Only a FDA approved wrap or pouch for steam sterilization must be used.
- Do not re-sterilize single use drills. These Drills are not designed to remain sharp and effective for more than one use.

- Pre-Vacuum method: Steam sterilise the abutments at 132-137°C (274-279°F) at 180-220kPa for 3-7 minutes. Dry for at least 10 minutes in the chamber. Only a FDA approved wrap or pouch for steam sterilization must be used.
- Do not re-sterilize single use drills. These Drills are not designed to remain sharp and effective for more than one use.

PROCEDURAL PRECAUTIONS

Thorough screening of prospective implant candidates must be performed. A systematic and coordinated plan delineating the responsibilities of each member of the team should be developed and followed. An evaluation of implant patients should include the following steps:

- Elicit and record a comprehensive medical and dental history and consider the relevance of that information to the individual case.
- Visual inspection as well as appropriate radiographs are essential to determine anatomical landmarks, occlusal conditions, periodontal status, and adequacy of bone.
- Cone beam and lateral cephalometric radiographs and tomograms may also be beneficial.

During the planning phase it is important to determine if the available bone dimensions are adequate for implant placement and to confirm that the available occlusal space is sufficient to accommodate the proposed abutment and final restoration. 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.

Do not reuse Implants, Cover screws, Temporary Abutments and Abutments. These are single-use products. Re-using these components may result in damage on the surface or critical dimensions. This may result in performance and compatibility degradation. The removal of proteins from the surface of components is extremely difficult and these proteins, when implanted, can lead to secondary infections.

POTENTIAL ADVERSE EFFECTS

Dental implant therapy has normal contraindications and risks that are extensively documented in the dental implant literature.

POST-PLACEMENT PROCEDURES

The following considerations should be reviewed prior to the restorative phase:

- Quantity, quality and health of soft and hard tissues
- Implant stability
- Implant position and abutment selection
- Occlusal analysis
- Oral hygiene assessment

MR SAFETY

These products have not been tested for MRI safety, however, an analysis and review of the literature has shown that the risks of scanning a Southern Implants implant system are not of concern under the following conditions:

- a static magnetic field of 1.5 Tesla and 3 Tesla.
- a magnetic field with a field gradient of 30T/M (3000G/cm).
- a whole body specific absorption rate (SAR) of 2W/kg, for 15 minutes of scanning.

STORAGE AND HANDLING

Devices should be stored at room temperature. Refer to the individual product packaging label and the corresponding manual (CAT-2004, CAT-2005, CAT-2020) for special handling instructions.

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:

SOUTHERNIMPLANTS®
novative Treatment Solutions

South Africa – Headquarters 1 Albert Road, Irene, RSA
T: +27-12-667-1046 | **E:** info@southernimplants.com

EC REP
Southern Implants Europe AB Holmgatan 30, S-791 71, Falun, Sweden
E: ecrep@southernimplants.com

Subsidiaries

Australia
Southern Implants Australia
+61-2-8076-9337
info@southernimplants.com.au

Spain and Portugal
Southern Implants Ibérica
T: +34 935 053 507
E: info@southernimplants.es

United Kingdom and Ireland
Southern Implants UK
T: +44-20-8899-6845 / 6 / 7
E: info@southernimplants.co.uk

USA and Canada
Southern Implants North America Inc.
T: +1-561-472-099
E: customercare@southernimplants.com