P.O. Box 605, Irene 0062
South Africa
Tel: + 27 12 667-1046
Fax: + 27 12 667-1029

CAT-5015-00

INSTRUCTIONS FOR USE OF OSSEOINTEGRATED FIXTURE PRODUCTS

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

All Southern Implants' products are intended to be used by appropriate 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 osseointegrated fixtures are intended for use as bone anchors for a prosthesis for the cosmetic rehabilitation of a patient who has small section of bone and connecting soft tissue missing. This could be caused by traumatic accidents, oncology resection or congenital defects.

DESCRIPTION

Southern Implants manufactures osseointegrated fixtures from biocompatible titanium and restorative components from titanium, titanium alloy, gold alloy and a variety of polymers. The "cast-to" gold abutments are made from a specific gold alloy so that technicians can cast precious and semi-precious metals onto these components.

For specific product descriptions refer to individual product packaging labels.

CONTRAINDICATIONS

Contraindications include: (1) cases where the remaining bone is too diminished to allow implant installation, (2) patients allergic to titanium, (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, infections around the implant site, or malignancies, (6) patients who have uncontrolled diabetes or blood disorders.

WARNINGS

For the safe and effective use of osseointegrated fixtures, it is strongly suggested that specialised training be undertaken, including hands-on training to learn proper technique 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 osseointegrated fixtures have only been validated for use with the corresponding Southern Implants abutments and accessories. Although care has been taken to create interfaces that are equivalent to similar products on the market, Southern Implants cannot guarantee outcomes obtained using components from other manufacturers. Please refer to the 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) "CONSULT INSTRUCTIONS FOR USE"
6) "CAUTION"
7) "DO NOT RESTERILIZE"





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8) CE MARK (if applicable) CE 0086

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

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 sterile. 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 container or seal is damaged or opened.

2) Other sterile components are packed in a peel pouch and sterilised by gamma irradiation. Labelling information is located on the bottom half of the pouch inside the packet. Sterility is assured unless the pouch is damaged or opened.

3) Other non-sterile components used in the laboratory are supplied clean but not sterile. These are: laboratory analogs, castable waxing sleeves, casting precision tools and gold abutments with plastic sleeves. Labelling information is located on the bottom half of the pouch inside the packet.

STERILITY

All implants and some abutments are shipped sterile and intended for single use prior to the expiration date (see packaging label). Again, 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 cleaning and sterilization procedure guidelines (CAT-1039) prior to use.

SURGICAL AND PROSTHETIC PROCEDURES

For detailed information of the surgical and prosthetic products, and recommended drilling protocol, refer to the product catalogues CAT-2010 and CAT-2036

CLEANING

- Please Refer to CAT-1039
- Used instruments should be soaked immediately in instrument cleaning solution to avoid the drying of blood 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 cleaned by material type.
- Instruments and trays can be cleaned and disinfected in a dedicated dishwasher or alternatively by hand, followed by an ultrasonic bath with a detergent appropriate for surgical instruments.
- Instruments and trays must be rinsed and dried thoroughly.

STERILIZATION

- Please Refer to CAT-1039
- Instruments and trays should be autoclaved at 121°C or 250°F for 30 minutes with a sufficient drying cycle to avoid instruments corrosion.
  Do not re-sterilize single use drills. These Drills are not designed to remain sharp and effective for more than one use.

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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 history and consider the relevance of that information to the individual case.
- Visual inspection and radiographs are essential to determine anatomical landmarks and adequacy of bone.

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 prosthetic 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 issues. The removal of proteins from the metal (such as titanium) is extremely difficult and it can lead to secondary infections

POTENTIAL ADVERSE EFFECTS

The following adverse effects may occur, particularly if correct trained use of the product is not followed:

- Damage to anatomical structures during placement – leading to loss of function, bleeding, etc
- Loss of bone
- Infection

POSTPLACEMENT 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

The peri-implant area should be constantly cleaned and monitored by the patient and reviewed at check-up for signs of infection

STORAGE AND HANDLING

Devices should be stored at room temperature. Refer to the individual product packaging label and the corresponding manual for special handling instructions. IMPLANTS MUST NOT BE TOUCHED DIRECTLY. They must be handled and placed by the instruments provided. If an implant is dropped onto the floor it should not be used.

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 (Pty) Ltd
P O Box 605
Irene 0062
South Africa

Tel: -27-12-6671046
Fax: -27-12-6671029

Manufacturer:
1 Albert Road
Irene 0062
South Africa

European Representative:
Building 3, Chiswick Park
566 Chiswick High Road
Chiswick
London W4 5YA
United Kingdom

Americas
225 Chimney Corner Lane
Suite 3011
Florida 33458
USA