

INSTRUCTIONS FOR USE OF DENTAL IMPLANT PRODUCTS

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

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 for use as anchors of fixed or semi-fixed dental crowns, bridges and overdentures in patients with partial or full edentulism of the upper or lower jaw.

DESCRIPTION

Southern Implants manufactures dental implants 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 dental technicians can cast precious and semi-precious metals onto these components. The ceramic abutments are made from 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 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, 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.

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) CE MARK (if applicable)



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

Rx only

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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 dental 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. It is not recommended to 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** and **PROSTHETIC MANUALS**.

CLEANING

- 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 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

- Instruments and trays should be autoclaved at 132°C - 135°C or 270°F - 275°F for 20 minutes with a sufficient drying cycle to avoid instruments corrosion.
Do not re-sterilize single use drills.

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 panoramic and apical radiographs is essential to determine anatomical landmarks, occlusal conditions, periodontal status, and adequacy of bone.
- Lateral cephalometric radiographs and tomograms may also be beneficial.

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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.

POTENTIAL ADVERSE EFFECTS

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

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
- Occlusal analysis
- Oral hygiene assessment

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.

CAUTION: (USA ONLY)

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For Technical Assistance or additional product literature, please contact:

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