SOUTHERN IMPLANTS (Pty) Ltd
PO Box 605, Irene 0062, South Africa

FOR-X7-00

INSTRUCTIONS FOR USE OF DENTAL IMPLANT PRODUCTS

INDICATIONS
The Implants are indicated for use as an anchor for fixed or semi-fixed dental crowns or bridges in patients with partial or full edentulism of the upper or lower jaw. A SUCCESSFUL OSSEOINTEGRATED IMPLANT WILL ACHIEVE A FIRM AND DIRECT CONNECTION BETWEEN THE LIVING BONE AND THE SURFACE OF THE THREADED TITANIUM IMPLANT WHEN SURGICALLY IMPLANTED UNDER CONTROLLED CONDITIONS.

DESCRIPTION
The Implants are made from specific titanium grades for surgical implantation. Similarly, Cover Screws, Healing Abutments and most Abutments are made from these same grades of titanium. 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 alumina, zirconia, and zirconia-toughened alumina.

LABELLING SYMBOLS
The following symbols are used on the packaging labels:

1) "USE BY"
2) "BATCH CODE" — LOT
3) " DO NOT REUSE"
4) SYMBOL FOR METHOD OF STERILISATION USING IRRADIATION — STERILE R
5) "ATTENTION, SEE INSTRUCTIONS FOR USE"
6) "i" INTERNAL DRIVE IMPLANT — i
7) CE MARK — CE

PACKAGING
1) Regular 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) Zygomatic Implants: The implants are placed in a peel pouch with the fixture mount uppermost. 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) Sprint Implants: The implants are placed in a hollow tube and the tube is placed in a peel pouch. The implants are packed with the correct impression coping and healing cap, each in their own peel pouch within the big peel pouch. Labelling instructions are located at the bottom half of the pouch inside the packet. Sterility is assured unless the pouch is damaged or opened.
4) Other sterile components: All drills, cover screws, temporary abutments and prosthetic parts that are commonly used in surgery are packed in a peel pouch and sterilised by gamma radiation. Labelling information is located on the bottom half of the pouch inside the packet. Sterility is assured unless the pouch is damaged or opened.
5) Other non-sterile components: Items that are generally used in the Laboratory are supplied clean but not sterile. These are: Laboratory analogues, Castable waxing sleeves, Impression copings, casting precision tools and Gold abutments with plastic sleeves. Labelling information is on the bottom half of the pouch inside the packet.

SURGICAL AND PROSTHETIC PROCEDURES
Please refer to the following manuals for detailed instructions for use:
Prosthetic and Laboratory Manual (FOR-T3), 1st and 2nd stage Surgery (FOR-U6), Zygomatic Implants (FOR-C8), Sprint Implants (FOR-Q8), Tapered Implants (FOR-D8), Simplex (FOR-T5), Co-Axis Implants (FOR-M9), Passive Abutment (FOR-T9), Instruments (FOR-V4), Torque-Wrench (FOR-E2), I-Series Implants (FOR-C9), Compression Screw Implants (FOR-C6), Compression Implants Drill Protocol (FOR-E6), Osteotome Site Preparation (FOR-L5), M-Series implants (FOR-C5), Morse Taper Implants (FOR-C4). Which hex drivers fit which components? (FOR-F1), Drilling protocol for IBT Implants. Step back technique (FOR-D7), Drill sequence for BAT Implants (FOR-K8a), Drill Sequence for BBBT Implants (FOR-K8b)

CLEANING
After surgical contamination, the following guidelines can be used:

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Surgical drills- Rinse with luke-warm water for three minutes. Sonicate for 10 minutes in an ultrasonic cleaner using enzymatic detergent diluted with tap water (Follow manufacturer's guidelines). Sonicate for 5 minutes in Ethanol.
Surgical and prosthetic tools- Rinse with luke-warm water for three minutes. Remove excess soil using a soft bristle brush. Sonicate for 5 minutes in an ultrasonic cleaner using enzymatic detergent or ethanol.
Surgical and prosthetic trays- Rinse in luke-warm water and remove soil with a soft bristle brush and enzymatic detergent. Rinse off with luke-warm water.
Prosthetic Components-Rinse in luke-warm water for three minutes. Two-part components should be disassembled. Sonicate for 10 minutes in an ultrasonic cleaner using enzymatic detergent diluted with tap water (Follow manufacturer's guidelines) Sonicate for a further 5 minutes using ethanol.

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 a 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 Southern Implants products, it is strongly suggested that specialised training be undertaken and that appropriate textbooks be studied. **THESE INSTRUCTIONS ARE NOT INTENDED AS A SUBSTITUTE FOR ADEQUATE TRAINING.** Responsibility for proper patient selection, for adequate training, experience in the placement of implants, and for providing appropriate information for informed consent rests with the practitioner. Improper technique can result in implant failure and/or loss of supportive bone.

PRECAUTIONS
Thorough screening of prospective implant candidates must be performed. 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. Electro-surgery should not be attempted around metal implants, as they are conductive.
Patients who experience convulsions due to existing medical conditions should be given special consideration with regards to the restorative treatment selected.
Do not reuse implants, Cover screws, Temporary Abutments and Abutments. These are single-use products.

ADVERSE EFFECTS
Mechanical fracture of Implants or bridges can occur. A blow to the mouth or jaw, or stress concentration from the bridge, could result in such mechanical failures. Do not use small diameter implants (less than 4mm) in high load applications. Mobility, bone loss, and/or pain and infections may indicate that the Implant is failing. On rare occasions when the Implant fails to osseointegrate, the implant must be removed. The bone will heal and the condition of the jaw and mouth will be virtually the same as if the procedure had not been performed. Loss of Implant anchorage (failure to osseointegrate) and loss of bridge(s) are possible occurrences after surgery. Lack of quantity and quality of remaining bone, infections, and generalised diseases (diabetes, etc.) are some potential causes for loss of anchorage.

SURGICAL COMPLICATIONS
The implant procedure has risks, including localised swelling, tenderness of short duration, and dryness of the mouth. These are extensively documented in the dental literature. Numbness of the lower jaw and chin region following lower jaw surgery, and of the tissue beside the nose following upper jaw surgery, is a possible side effect of the surgery. Though it would most probably be of a temporary nature, in very rare cases, the numbness has been permanent. Gingival-mucosal (gum tissue) ulceration, tissue reaction, or infection may occur, but generally responds to local care.

SHIPPING AND HANDLING
These implants have been cleaned and sterilised, and are ready to use. Sterile packages containing the implant should be opened onto a sterile field, and are best handled with titanium instrumentation.

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:

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