SOUTHERNIMPLANTS
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PRO-6038-06

INSTRUCTIONS FOR USE OF DENTAL IMPLANT PRODUCTS

GUIDELINES FOR THE PROVISION OF DENTAL IMPLANTS

Dental implants have become an accepted method for tooth replacement and should be presented by dentists to patients as an alternative to replacing missing teeth. Patients in need of tooth replacement should be informed about dental implants, including the potential benefits, long-term survival statistics, risks and potential complications. In addition, they should be informed about the importance of maintenance and long-term follow up, including their specific responsibilities regarding the same. Fortunately, there is a wealth of evidence based research available that dental professionals may utilize to inform their patients. In addition, dental professionals may find answers to critical questions regarding implant therapy in the following guidelines developed by the Academy of Osseointegration (AO) based on recognized standards of care and the results of AO's 2006 Consensus Conference on the State of the Science on Implant Dentistry.

DEFINITION

Definition of dental implant (adapted from *The Glossary of Prosthodontics Terms*): A prosthetic device made of alloplastic material(s) implanted into the oral tissue beneath the mucosa and within the bone to provide retention and support for a fixed or removable dental prosthesis.

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.

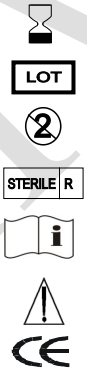
DESCRIPTION

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 zirconia.

LABELLING SYMBOLS

The following symbols are used on the packaging labels:

1) "USE BY"
2) "BATCH CODE"
3) " DO NOT REUSE"
4) "STERILISED USING IRRADIATION"
5) "CONSULT INSTRUCTIONS FOR USE"
6) "CAUTION"
7) CE MARK



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) 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.
3) 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 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.
4) 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, casting precision tools and Gold abutments with plastic sleeves. Labelling information is on the bottom half of the pouch inside the packet.

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SURGICAL AND PROSTHETIC PROCEDURES

The surgical technique is based on the pretreatment evaluation and the type of implant to be utilized. The following should be considered:

- Aseptic technique
- Appropriate use of surgical templates
- Surgical template utilized
- Appropriate postoperative instructions

Please refer to the following manuals for detailed instructions for use:
Prosthetic and Laboratory Manual (CAT-2001), 1st and 2nd stage Surgery (CAT-2024), Cranio-Facial (CAT-2036), Sprint Implants (FOR-Q8), Simplex (FOR-T5), Passive Abutment (CAT-1008), Instruments (CAT-2006), Torque-Wrench (CAT-1001), One Piece Implants (CAT-1083), Osteotome Site Preparation (CAT-1004), IT Implants (CAT-2005). Which hex drivers fit which components? (CAT-1007), Tri-nex Implants (CAT-2004). Externally Hexed Product Catalogue Version 8 (CAT-2020). Finger Implants Catalogue (CAT2010).

CLEANING

After surgical contamination, the following guidelines can be used:
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. Place the components into a sterilisation bag or drill tray and autoclave for 15 minutes at 121°c (250°f).
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. Rinse all tools in running water and dry. Place the tools into a sterilisation bag or instrument tray and autoclave for 15 minutes at 121°c (250°f).

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 and dry. Place in cassette or sterilisation bag and autoclave for 15 minutes at 121°c (250°f).
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. Place the components into a sterilisation bag and autoclave for 15 minutes at 121°c (250°f).

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. We have no control over the application and processing of our products, which are the responsibility of the user. We will not accept liability for damage arising thereof.

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 understand 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.

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. Patients who are on intravenous bisphosphonates have been shown to be at risk to develop osteonecrotic jaw disease (ONJ) following oral surgical procedures. At present, many organizations, including the American Association of Oral and Maxillofacial Surgeons, have recommended against any elective surgery involving oral osseous structures for patients who have been on intravenous bisphosphonates for any period of time. Since there is no agreed upon half-life of these medications, cessation does not reduce or eliminate the risk of ONJ. Oral bisphosphonates carry a much smaller risk of than intravenous bisphosphonates, especially if used less than 3 years. However, the development of ONJ has been reported by patients on short-duration, low-dose oral bisphosphonates. Patients on oral bisphosphonates should be advised of the potential risks of developing ONJ, although there is apparently no contraindication to treatment at present. The potential risks to develop ONJ have been outlined be the American Dental Association.

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.
Temporary symptoms: Swelling, phonetic difficulties, pain, gingivitis.

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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. Placement of an implant: Do not exceed 15rpm when inserting the implant and do not use a high torque. The insertion tool has a predetermined breaking point.

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

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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