GDT DENTAL IMPLANTS
INSTRUCTIONS FOR USE

Made For GDT Implants
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USER'S MANUAL FOR GDT PRODUCTS

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

All GDT Dental Implants products are intended to be used by appropriate trained and licensed professionals.

INDICATIONS

GDT 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.

MOR Spiral Implant – More suitable for upper jaw and soft bone D3 / D4 which can be used in all types of surgical procedures – two stages, one stage, immediate loading, and flapless for all types of ridges. Can be placed in the healed bone or immediate replacement after extraction

CFI Cylindrical Implant – Suitable for dense bone D1 / D2 which can be used in all types of surgical procedures – two stages, one stage, immediate loading, and flapless for all types of ridges. Can be placed in the healed bone or immediate replacement after extraction

DESCRIPTION

GDT Implants manufactures dental implants from biocompatible titanium and restorative components titanium alloy 6AL 4V ELI and a variety of polymers.

For Special product descriptions, please refer to individual product packaging labels.

CONTRAINDICATIONS

Contraindications include:

a) Cases where the remaining jaw bone is too diminished to allow implant installation;
b) Patients allergic to titanium;
c) Patients with insufficient mental health precluding patient cooperation;
d) Patients who abuse drugs or alcohol;
e) Patients who have conditions such as but not limited to myocardial infarct within the last year, oral infections, or malignancies;
f) Patients who have uncontrolled diabetes or blood disorders.

WARNINGS

For the safe and effective use of dental implants, it is strongly suggested that specialized 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.

GDT Implants will not accept liability for damage caused by improper implant treatment.

LABELLING SYMBOLS

The following symbols are used on the packaging labels:

USE BY DATE	
CATALOG REFERENCE	REF
LOT NUMBER	LOT
STERILIZED USING IRRADIATION	STERILE R
MEDICAL DEVICE	MD
CONSULT INSTRUCTIONS FOR USE	
CAUTION	
DO NOT RE-USE	
DO NOT USE IF PACKAGE IS DAMAGED	
DO NOT RESTERILIZE	
TEMPERATURE	40°C 104°F 5°C 41°F
DATE OF MANUFACTURE	
SYMBOL FOR "USE BY PRESCRIPTION ONLY"	Rx only
REGULATORY COMPLIANCE	CE
MANUFACTURER	
EUROPEAN REPRESENTATIVE	EC REP

PACKAGING

1) All implants are delivered in sterile double packaging. The outer box houses a vial that includes the pre-mounted implant covered with implant guard.

Each pack includes cover screw and carrier mount.

The pack is labeled with the implant type, length and color coded for implant diameter. A sticky label displays all pertinent information regarding the implant. Two labels are supplied in the package.

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2) Implant and all related components in tubes pack are sterilized by gamma irradiation. Labeling information is located in one of the section inside the pack. 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 abutments with plastic sleeves and other prosthetic components.

CONDITION FOR USE, TRANSPORTATION AND STORAGE

The implant sets will transport only in the original package and inside of good harder cover package. If the original package is damage do not use it. The product must be stored in a dry place, away from sunlight, moisture and sources of heat. It should be stored at room temperature 5° C to 40°C (41°F to 104°F).

STERILITY

All dental implants 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 Surgical Manual prior to use.

CLEANING AND STERILIZATION

Please Refer to Instructions for Sterilization and Instrument Care.

PROCEDURAL PRECAUTIONS

All components must be checked before use.

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.

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 osseointegratin.

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

Site preparation for implantation process in bone:

- Drill using a 2 mm Twist drill.
- Drill using a 2.8 mm Twist drill. If the bone is very soft use the 2.8 mm Twist drill just to penetrate the cortex.
- Begin by inserting the implant into the prepared site. The variable thread design and the bone condensing properties of the thread and core contribute to the achievement of sufficient retention and stabilization surrounding the implant.

POTENTIAL ADVERSE EFFECTS

Short-term risks associated with the use of these products include anesthetic and surgical risks, psychological and psychiatric risks, pain, gingivitis, speech problems.

Long-term risks include nerve damage, bone loss, local or systemic bacterial infections, infectious endocarditis.

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.

TABLE OF SCREW SETTING TORQUE (N-CM) AND RECOMMENDED DRILL SPEED:

PROSTHESIS	TORQUE (N-CM)
HEALING CAP	15
ABUTMENTS	25
MULTI-UNIT ABUTMENTS	30-35
CLICK ATTACHMENT	30-35
BALL ATTACHMENT	30-35
MULTI-UNIT SCREW	20-25

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