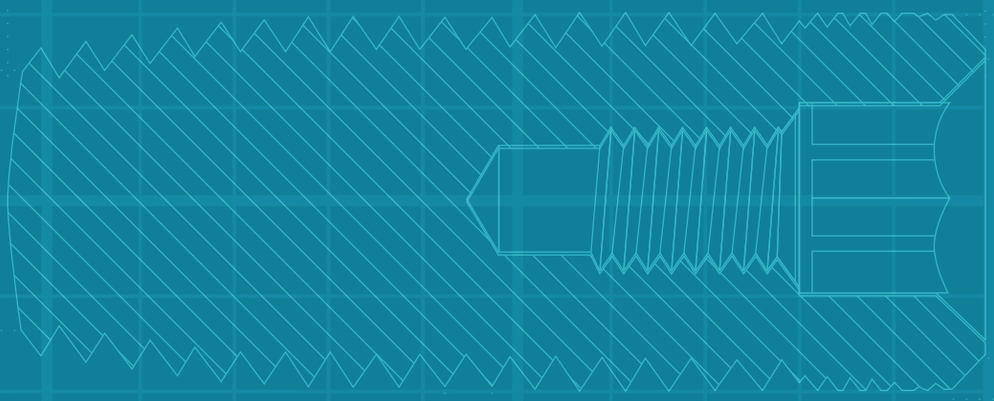
ENGINEERING THE FUTURE



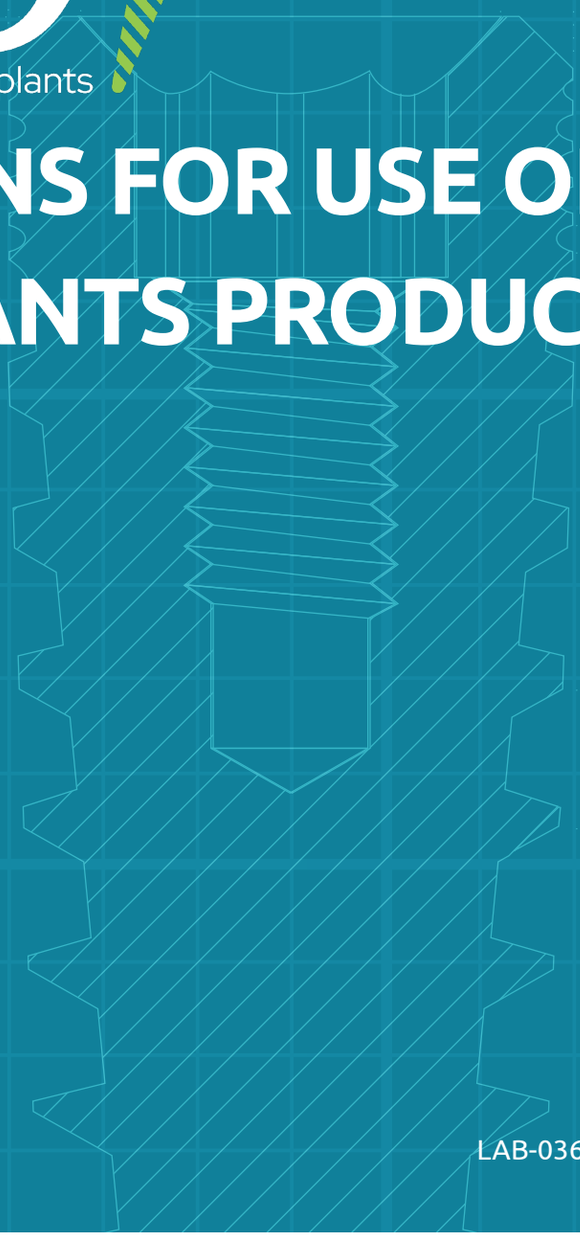
IMPLANTOLOGY

MADE IN ISRAEL

GD Dental Implants

INSTRUCTIONS FOR USE OF DENTAL IMPLANTS PRODUCTS

ALL SOLUTIONS FOR A PERFECT SMILE



LAB-036.01 Rev 01

Instructions For Use

This document applies to GDT Dental Implants restorative and laboratory components. All GDT Dental Implants products are intended to be used by approproate and licensed professionals.

Indications

GDT 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.
Spiral Implant- 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 flap less for all tapes of ridges. can be in the healed bone or immediate replacement after extraction.
Classic Implant- Suitable for dense bone D1/D2 which can be used in all types of surgical procedures - two stages, one stage, immediate loading and flap less for all types of ridges. Can be placed in the healed bone or immediate replacement after extraction.

Description

GDT Dental Implants are made of biocompatile titanium and restorative components titsnium alloy 6Al 4V Eli and variety of polymer (Dalarin).
For special product descriptions, please refer to individual packaging labels.

Model and Diamentions

Model	Description	Diameter (Ø)	Length
ABA	Spiral Implant	3.5, 3.75, 4.2, 5.0, 6.0 mm 4.2, 5.0, 6.0 mm	8, 10, 11.5, 13 ,16 mm 6 mm
CFI	Cylindrical Implant	3.3, 3.75, 4.2, 5.0, 6.0 mm 3.75, 4.2, 5.0, 6.0 mm	8, 10, 11.5, 13 ,16 mm 6 mm
CON	Spiral Conical Implant	3.5, 4.3, 5.0 mm	6, 8, 10, 11.5, 13 ,16 mm

Contraindications

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.
G) Involuntary tooth grinding during sleep, bruxism.

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, biomechanics requirements and radiographic evaluations.

These instructions are not intended as a subtitute for adequate training. GDT Dental Implants company will not accept liability for damage caused by immproper implant treatment

GDT
Dental Implants

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Labelling Symbols

Ther following symbols are used on the packaging labels:

USE BY DATE	
CATALOG No.	Ref ABA XXXX
BATCH CODE	LOT
DO NOT RE-USE	
STERILIZED BY IRRADIATION	STERILE R
CAUTION, CONSULT ACCOMPANYING DOCUMENTS	
PRODUCT DESCRIPTION	ABA x.x Lxx mm
REGULATORY COMPLIANCE	CE
MANFACTURER	
DO NOT USE IF PACKAGING IS BROKEN ORDAMAGED	
EUREPRESENTATIVE	EC REP
DO NOTRESTERILIZE	
MAGNETIC RESONANCE CONDITIONAL	MR
KEEP THE PRODOCT IN A DRY PLACE AWAY FROM WATER AND RAIN	
STORE AT TEMPERATURE 15°C to 25°C	+15°C +25°C
KEEP AWAY FROM SUNLIGHT	
MEDICAL DEVICES	MD
MADE IN ISRAEL	IL
UNIQUE DEVICE IDENTIFIER	UDI
DATE OF PRODUCTION	

Packaging

1. All implants are delivered ion sterile double packaging. The outer box houses a vial that includes that pre-mouthed implant covered with the 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 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 component used in the laboratory are supplied clean but not sterile. These are: laboratory analogs, capable waxing sleeves, castable waxing sleeves, casting precision tools and abutments with plastic sleeves and other prosthetic components.

Sterility

All dental implants are shipped sterile and intended for single use prior to the expiration date (see packaging label). Again, sterility is as;sured 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 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. The removal of proteins from the metal (such as titanium) is extremely difficult and it can lead to secondary infections.

Changes in Performance

It is the clinician's responsibility to inform the patient about the precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety It is the responsibility of the patient to seek medical care if any of the side effects occur.

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 inserting the implant into the under prepared site. the variable thread design and the bone condensing properties os the thread and core contribute to the achievement of

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sufficient retention and stabilization surrounding the implant.

- The maximum torque 45Ncm insertion torque.

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, water and sources of heat.
It should be stored at room temperature 15°C to 25°C.

Potential Adverse Effects

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

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