DTI Implant System
"We Produce Science"

TF.01_2.2-1
Ver. 3.0
English - FDA

INSTRUCTION FOR USE DENTAL IMPLANT SYSTEM

Manufacturer **DTI Implant Systems Inc.**
Head Office: Çavuşbaşı Cd. Aytekin Sk. No:5/1-2 Çekmeköy İstanbul Turkey
Factory: TÜBİTAK Gebze TEKSEB Kocaeli Turkey

CE 1984

	Manufacturer
	Production Date
	Use by Date
LOT	Batch Code
REF	Catalog Number
Rx Only	U.S. federal law restricts this device to sale by or on the order of a dental professional.
	Do not reuse
	Do not use if package is damaged
STERILE R	Sterilized using gamma radiation
	Keep away from sunlight
	Keep dry
	Caution, Consult accompanying documents

CAUTION: U.S. federal law restricts this device to sale by or on the order of a dental professional.

Product Description

DTI-1 SLA Implant System (for FDA 510(k) K170776) is an integrated system of endosseous dental implants with corresponding abutments, healing abutments, closure screws and surgical and prosthetic parts and instruments. DTI-1 SLA Implant System implants are solid screw implants comprised of a Titanium grade 5 with a bone anchorage SLA surface that is large-grit sandblasted and acid etched.

Intended use

The DTI-1 SLA Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.

Indications

The DTI-1 SLA Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.

Warning

Products must be secured against aspiration when handled intraorally. Aspiration of products may lead to infection or unplanned physical injury.
Avoid approaching the proximity of the mandibular nerve channel during implant bed preparation and implant insertion. Nerve damage may result in anesthesia, paraesthesia and dysesthesia.

Contraindications

Inadequate bone volume and/or quality, local root remnants, serious internal medical problems, uncontrolled bleeding disorders, inadequate wound healing capacity, not completed maxillary and mandibular growth, poor general state of health, uncooperative, unmotivated patient, drug or alcohol abuse, psychoses, prolonged therapy-resistant functional disorders, xerostomia, weakened immune system, illnesses requiring periodic use of steroids, uncontrollable endocrine disorders.
Allergies or hypersensitivity to chemical ingredients of materials used: titanium (Grade5).

Side effects, interactions and precautions; complications with DTI Implant Systems Information related to side effects, interactions and precautions; complications with DTI-1 SLA Implant System Information related to side effects, interactions and precautions; complications with DTI-1 SLA Implant System should be provided to the patient. Immediately after the insertion of dental implants, activities that demand considerable physical exertion should be avoided. Possible complications following the insertion of dental implants are:

Temporary symptoms

Pain, swelling, phonetic difficulties, gingival inflammation.

More persistent symptoms

Chronic pain in connection with the dental implant permanent paraesthesia, dysesthesia, loss of maxillary/ mandibular ridge bone, localized or systemic infection, oroantral or oronasal fistulae, unfavorably affected adjacent teeth, irreversible damage to adjacent teeth, fractures of implant, jaw, bone or prosthesis, aesthetic problems, nerve damage, exfoliation, hyperplasia.

Cautions/Precautions

Always select the largest diameter implant that can be supported by the available bone thickness, bone quality, inter-dental spacing, and anticipated mastication forces. Particular care should be taken to assure proper implant alignment where comparatively high loads are expected. Small diameter implants are not recommended for the posterior region.
A careful clinical and radiological examination of the patient should be performed prior to surgery to determine the psychological and physical status of the patient. Special attention should be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g. bone metabolism disturbances, previously irradiated bone in the head or neck area, diabetes mellitus, anticoagulation drugs/hemorrhagic diatheses, bruxism, parafunctional habits, unfavorable anatomic bone conditions, tobacco abuse, untreated periodontal diseases, acute infection of implant site, temporomandibular joint disorders, treatable pathologic diseases of the jaw and changes in the oral mucosa, pregnancy, inadequate oral hygiene).
Sterile handling is essential. Never use potentially contaminated components. Contamination may lead to infections.
The implants must be stored in a dry place in the original packaging, protected from direct sunlight and at room temperature. Improper storage may compromise essential material and design characteristics leading to device failure.
Do not re-sterilize DTI-1 SLA Implant System. Cleaning, disinfection and sterilization may compromise essential material and design characteristics leading to device failure.
Do not re-use DTI-1 SLA Implant System. Reuse of single-use devices creates a potential risk of patient or user infections.
Avoid corrections of the vertical position using reverse rotations (counterclockwise). This can cause loosening of the screw-retained transfer piece and may lead to a decreased primary stability.
The DTI-1 SLA Implant System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of DTI-1 SLA Implant System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
Small diameter implants (Ø 3.5) and angled abutments (15˚, 25˚) are not recommended for use in the posterior region of the mouth.

Pyrogenicity

Not tested for pyrogenicity.

Compatibility information

DTI Dental implants and the prosthetic lines DTI-1 SLA Implant System are available in a variety of configurations. Make sure that you use only DTI parts with the corresponding connection for the restoring of a DTI Dental implant for further information see the brochures “Basic Information” as mentioned in “Further Information”.
Only DTI Dental implants labelled with ‘Guided Surgery’ are suitable for insertion through DTI Guided Surgery templates. For additional information see “Basic Information on DTI Guided Surgery – DTI-1 SLA Implant System”.

Cleaning and disinfection

DTI-1 SLA Implant System are provided sterile and for single use only – They must not be cleaned and sterilized. DTI Implant Systems Inc. does not accept any responsibility for re- sterilized implants regardless of who has carried out re-sterilization or by what method.

Sterilization

DTI-1 SLA Implant System are delivered sterile. The intact sterile packaging protects the sterilized implant from outside influences and, if stored correctly, ensures sterility up to the expiration date. When removing the implant from the sterile packaging, rules of asepsis must be observed. The sterile packaging must not be opened until immediately prior to insertion of the implant. Implants with damaged sterile packaging must not be used. It is recommended to have a replacement implant at hand.
DTI abutments, healing screws and abutment screws are provided non-sterile and should be sterilized by the user. Validated sterilization method is;
Method: Moist heat sterilization according to EN ISO 17665.
Cycle: Saturated steam with fractional forced air removal
Exposure Time: 30 minutes
Temperature: 121°C (250°F)
Drying Time: For wrapped devices 30 minutes (minimum, in chamber)

Procedure

Consult the brochures “Basic Information” as mentioned in “Further Information” for a detailed step-by-step description.

Preoperative planning

The implant diameter, implant type, position and number of implants should be selected individually taking the anatomy and spatial circumstances into account. The specific measurements should be regarded as minimum guidelines and are further specified in the “Basic Information on the Surgical Procedures”.

Implant bed preparation

Thermal trauma prevents healing of a dental implant. Excessive rises in temperature must there-fore be minimized by following the “Guidelines for the use of DTI-1 SLA Implant System drills and instruments” regarding rotations per minute, intermittent drilling techniques and adequate cooling.
Insertion of the implant
A DTI-1 SLA Implant System can be placed either manually with the ratchet or with the aid of the hand piece. A maximum speed of 15 rpm is recommended.

Treatment of soft tissue, wound closure

Prior to wound closure, the appropriate closure screw or healing cap is selected and screwed on to the implant. Consult the corresponding package insert when using healing caps and closure screws.

Healing phase

DTI-1 SLA Implant System are suitable, within the scope of indications, for immediate and early restoration in single-tooth gaps and in an edentulous or partially edentulous jaw. Good primary stability and an appropriate occlusal load are essential. In case of immediate restoration: In partially edentulous jaws, two or more adjacent implants should be prosthetic ally connected. In edentulous jaws, at least 4 implants must be connected. For minimal healing time for relevant DTI-1 SLA Implant System refer to the “Basic Information on the Surgical Procedures”. Radiographic check is recommended after a healing phase before starting the prosthetic restoration.

Further Information

You will find further information regarding treatment recommendation and use of different types of DTI-1 SLA Implant System and other components of the DTI-1 SLA Implant System in the documentation that is available on request from DTI. Ensure that the following brochures, in particular the surgical brochures, are available.

Package inserts:

- “Guidelines for the use of DTI-1 SLA Implant System drills and instruments”
- “Instructions for the use of DTI-1 SLA Implant System closure screws, healing caps and healing abutments “

Please note

Practitioners must have knowledge of dental implantology and instruction in the handling of the DTI product described herein (“DTI Product”) for using the DTI Product safely and properly in accordance with these instructions for use.
The DTI Product must be used in accordance with the instructions for use provided by the manufacturer. It is the practitioner’s responsibility to use the device in accordance with these instructions for use and to determine if the device fits to the individual patient situation.
The DTI Product is part of an overall concept and must be used only in conjunction with the corresponding original components and instruments distributed by DTI Implant Systems Inc., its ultimate parent company and all affiliates or subsidiaries of such parent company (“DTI”). Use of products made by third parties, which are not distributed by DTI, will void any warranty or other obligation, express or implied, of DTI.

Validity

Upon publication of these instructions for use, all previous versions are superseded.