



DTI MONO-FLEX, MONO-BALL, MONO IMPLANT



	Manufacturer
	Production Date
	Use by Date
	Batch Code
	Catalog Number
	By Prescription Only
	Do not reuse
	Do not use if package is damaged
	Sterilized using gamma radiation
	Keep away from sunlight
	Keep dry
	Caution, Consult accompanying documents
	Double sterile barrier system
	Single sterile barrier system
	Medical Device
	Consult electronic instructions for use

Description of DTI Implant System

DTI Implant is a brand for implant materials for dental practices. The raw material of Mono Implant is Grade 5 Titanium. The abutment, prosthetic components for DTI Implant System are compatible with DTI Implant fixture only. Using this product in combination with products from other manufacturers may cause various problems including loosening and fracture due to incomplete locking and compatibility issues. Use DTI Implants only with related concept products. Refer to manual or the catalogue or our website (www.dtiimplant.com) for details. See the product label for the product code, specifications, manufacturing date, and expiration date.

Disclaimer of liability

This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instruction's recommendation of DTI Implant Systems. Non-recommended use of products made by third parties in conjunction with DTI Implant Systems products will void any warranty or other obligation, express or implied, of DTI Implant Systems.

The user of DTI Implant Systems products have the duty to determine whether or not any product is suitable for the particular patient and circumstances.

DTI Implant Systems disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of DTI Implant Systems products. The user is also obliged to study the latest developments in regard to this DTI Implant Systems product and its applications regularly. In cases of doubt, the user has to contact DTI Implant Systems.

Since the utilization of this product is under the control of the user, it is his/her responsibility. DTI Implant Systems does not assume any liability whatsoever for damage arising thereof.

Description

DTI Mono, Mono-Flex, Mono-Ball Implant is one-piece dental implant made of titanium with SLA surface.

Intended use

DTI Implants are dental implants intended to be used in the upper or lower jaw bone anchoring or supporting tooth replacements to restore chewing function.

Indications

DTI Implant Systems are designed for use in dental implant surgery. It replaces the natural tooth root surgically inserted into the upper or lower alveolar bone. The implant can restore the injured tooth by connecting abutment after osseointegration with the alveolar bone.

Contraindications

DTI Implants should not be placed in patients discovered to be medically unfit for the intended treatment. Prior to clinical intervention, prospective patients must be thoroughly evaluated for all known risk factors and conditions related to oral surgical procedures and subsequent healing. Contraindications include but are not limited to:

- Patient not prepared to undergo total oral rehabilitation
- Vascular conditions
- Uncontrolled diabetes
- Clotting disorders
- Anticoagulant therapy
- Metabolic bone disease
- Chemotherapy or radiation therapy
- Chronic periodontal inflammation
- Insufficient soft tissue coverage
- Metabolic or systemic disorders associated with wound and/or bone healing
- Use of pharmaceuticals that inhibit or alter natural bone remodelling
- Any disorders which inhibit a patient's ability to maintain adequate daily oral hygiene e.g., bruxism
- Uncontrolled parafunctional habits
- Insufficient height and/or width of bone
- Insufficient interarch space
- Treatment of children is not recommended until growth is finished and epiphyseal closure has occurred.
- Patients who are allergic or hypersensitive to titanium

Warnings

The following instructions are not sufficient to allow inexperienced clinicians to administer professional prosthetic dentistry. DTI Implants, surgical instruments, and prosthetic components must only be used by dentists and surgeons with training/experience with oral surgery, prosthetic and biomechanical requirements, as well as diagnosis and preoperative planning.

The implant site should be inspected for adequate bone by radiographs, palpations and visual examination. Determine the location of nerves and other vital structures and their proximity to the implant site before any drilling to avoid potential injury, such as permanent numbness to the lower lip and chin.

Absolute success cannot be guaranteed. Factors such as infection, disease, and inadequate bone quality and/or quantity can result in osseointegration failures following surgery or initial osseointegration. Dental implants must not be altered in any way. Implant mobility, bone loss or chronic infection may indicate implant failure. Do not reuse the implants. The reuse of such device on another patient is not recommended due to the risks of cross-contamination or infection. Implant cannot be re-sterilized.

DTI Implants have 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 implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Cautions

Procedural Precautions, Surgery: All efforts must be made to minimize damage to the host tissue, paying special attention to thermal and surgical trauma and to the elimination of contaminants and sources of infection. The surgical procedure requires a high degree of precision and care, and the limits for acceptable tissue handling are must narrower than in general oral surgery. Any divergence from the principle of least possible trauma at implant installation increases the risk of failure to establish osseointegration.

All drilling procedures should be performed at approximately 800-1200 rpm. All drilling and pretapping procedures require the use of dedicated, sharp instruments under constant and profuse irrigation for cooling. Implants are ideally installed in a stable manner. All instruments used in surgery must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components. Because of the small size of implant components and instruments, care must be taken that they are not swallowed or aspirated by the patient. After the implant installation, the surgeon's evaluation of bone quality and initial stability will determine when implants may be loaded.

Procedural Precautions, Prosthetics: Especially important is proper stress distribution: passive adaptation and fitting of the bridge to the implant abutments; adjusting occlusion to the opposing jaw; avoiding excessive transverse loading forces, particularly in immediate loading cases. Because of the small size of prosthetic components, care must be taken that they are not swallowed or aspirated by the patient.

Caution for Patient: To keep completely the oral hygiene. Do not apply bite force until final prosthetic placement.

Surgical Procedure:

1. During drilling procedures bone quality should be considered (Please see Table 1)

Recommended drill sequences based on bone quality: Table 1

Implant Drill Sequence		
Ø 2,8 Fixture	Lance Drill	
Ø 3,5 Fixture	Lance Drill	Ø 2,3 Drill

Drilling must proceed at high speed (recommended 800 rpm - max. 1200 rpm) under constant and profuse external irrigation by sterile saline at room temperature.

Depth measurement system: the depth gauge has a true depth measurement system.

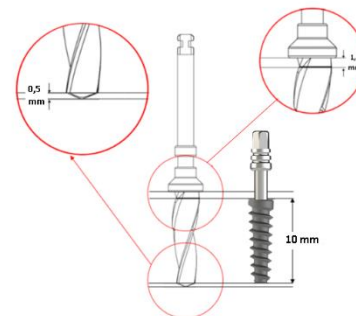
All drills and components are marked to prepare the site to the correct depth and obtain a secure and predictable position with laser marking.

Caution: Drills are 0,5 mm longer than the implant when seated. Allow for this additional length when drilling near vital anatomical structures. (Please see Picture 1 for drill reference lines).

Caution: Drills extend up to 1,5 mm longer than the laser marking. Allow for this additional length when drilling near vital anatomical structures.

Note: Final vertical positioning depends on several parameters, including esthetics, tissue thickness and available vertical space.

Note: It may use drill extension in cases where adjacent natural teeth and the motorhead intersect to provide the drill to reach the desired depth.



Picture 1 shows Ø 2,3 x 10 dental drill and Ø 3,5 x 10 mm implant

2. Prepare implant site. When using a flapless approach add-on soft tissue height to drill depth.
3. Measure the final depth of implant site for applicable implant length using depth.
4. Open the implant package and pick up the implant from inner casing by applying light pressure on the implant driver and carefully turn the implant sleeve counter clockwise until implant driver is fully seated. DTI implants are ideally installed with low speed, max 25 rpm, using drilling device or by hand using surgical driver.
5. Place and tighten the implant. For DTI Implant Ø2.8 and Ø3.5 Fixture use maximum 40 Ncm installation torque.

Cleaning and sterilization instructions

DTI Implants are delivered sterile for single use only prior to the labelled expiration date.

Warning: Do not use device if the packaging has been damaged or previously opened.

Caution: Implants are single use product and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause cross contamination.

All Drills are delivered nonsterile and intended for re-use. Prior to re-use, clean, disinfect and seal the product in a pouch and steam sterilize using the recommended parameters.

Warning: Use of non-sterile device may lead to infection of tissues or infectious diseases. Steam sterilizes at 121°C for 20 minutes.

Storage and handling

The product must be stored in a dry place in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics leading to failure.

Disposal

Products that have come into contact with the patient should be treated as medical waste. Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

Manufacturer



DTI İmplant Sistemleri San. Tic. A.Ş.
Head Office & Factory: Barış SB Mah.
5001 Sok. TÜBİTAK-MAM TEKSEB Sitesi
DTI İmplant No:16 Gebze, Kocaeli, Turkey
Phone: +90 (262) 642 0 384
E-mail: info@dtiimplant.com