

1. Introduction

- This document pertains to the DUAL IMPLANT SYSTEM, including dental implants, abutments, and associated surgical, restorative, and dental laboratory components.
- All DUAL IMPLANT SYSTEM products are intended for use exclusively by appropriately trained and licensed dental professionals.
- Prior to using the DUAL IMPLANT SYSTEM, the operating surgeon or practitioner must:
 - Carefully review the indications, contraindications, warnings, and instructions provided in this document, as well as any other product-specific information.
 - Fully comply with all guidelines to ensure safe and effective use.
- Additional details beyond what is provided in this document can be found in the technical description of the product or the relevant catalogue .
 - For comprehensive product-specific information, including technical descriptions and descriptions of surgical and restorative techniques, it is strongly recommended that users attend specialized training courses.

2. Description

- **Description of the DUAL Implant System**
 - The DUAL Dental Implant System is a comprehensive, integrated solution consisting of:
 - Endosseous dental implants
 - Corresponding abutments
 - Healing abutment
 - Covering and fixing screws
 - Surgical and prosthetic instruments
- **Materials and Design**
 - All DUAL implants are crafted from biocompatible Titanium Alloy (Ti-6Al-4V ELI), composed of titanium, aluminum, and vanadium. This material is recognized by the human body and ensures maximum bone anchorage.
 - The implants feature a tapered body with an internal hexagonal connection , enhancing precision and stability during placement.
 - The implant section is specifically designed to:
 - Facilitate ease of implantation
 - Provide a greater surface area to promote osseointegration
 - The implant surface is treated to further enhance osseointegration.
- **Models of the DUAL Dental Implant System**
 - The system includes four models as finished products:
 1. Model A: Single-Piece Implant — delivered in a sterile barrier package
 2. Model B: Two-Piece Implant — delivered in a sterile package with a covering screw
 3. Model C: Abutment — delivered in a barrier package, non-sterile finished product
 4. Model D: Abutment + Connecting Screw — delivered in a barrier package, non-sterile finished product

3. Intended Use / Indications

All DUAL implants are designed to replace missing, compromised, or damaged teeth in the upper or lower jaw. They serve as an anchorage system for prosthetic superstructures, enabling effective tooth restoration.

4. Contraindications

- A. Absolute Contraindications**

Implants must not be placed in patients with the following conditions:

- Recent myocardial infarction (within six months of an attack)
- Cerebral infarction or apoplexy in severe cases, especially when the patient is on anticoagulant therapy
- Severe immunodeficiency or patients undergoing strong chemotherapy
- Severe neuropsychiatric conditions, mental disabilities, or narcotic drug addiction
- Concurrent use of bisphosphonates
- Youths under the age of 15
- Allergies or hypersensitivity to implant materials, such as titanium alloy (Ti-6Al-4V Eli)

- B. Relative Contraindications**

Implant placement should be carefully considered in patients with the following conditions:

- Diabetes (particularly insulin-dependent)
- Angina pectoris
- Seropositivity (clinical AIDS is an absolute contraindication)
- Significant tobacco use
- Certain mental health disorders
- History of radiotherapy to the neck or face (depending on dose, location, and cancer specifics)
- Autoimmune diseases
- Drug or alcohol dependency
- Pregnancy
- Diseases of the oral mucous membranes
- Periodontal disease: gums must be cleaned and the disease stabilized prior to implant placement
- Use of anticoagulation drugs or presence of hemorrhagic diatheses
- Temporomandibular joint (TMJ) disorders
- Poor occlusal relationships (unbalanced bite between the upper and lower teeth)
- Poor oral hygiene
- Insufficient bone quantity to support the implant
- Infections in adjacent teeth (e.g., pockets, cysts, granulomas) or major sinusitis
- Severe bruxism or clenching, which can cause bone loss, screw loosening, component fracture, or implant failure
- Exposure to radiation therapy or chemotherapy, which may affect implant health

- **Additional Notes:**

- If implant placement occurs under conditions of absolute contraindications, the manufacturer will disclaim any warranty obligations.

5. Patient Population

- **Age and Gender:**

- There is no conclusive evidence suggesting that age or gender significantly impacts the outcome of osseointegration in either the short or long term.
- There is no upper age limit, provided the patient can tolerate the surgical procedure and maintain proper postoperative self-care.
- However, implant treatment should be delayed in young individuals until skeletal growth is complete.
- Patients should ideally be at least 15 years old with sufficient bone volume and maturity to reduce the risk of postoperative complications related to ongoing bone growth.
- Clinicians should note that facial growth can continue beyond 15 years of age, which may lead to complications over time

6. Warnings & precautions

6.1 Warnings

- **Professional Use Only**

- The DUAL Implant System must be used exclusively by trained and licensed dental professionals.
- Hands-on specialized training is strongly recommended to ensure proper technique, treatment planning, and patient safety.

- **Patient Evaluation**

- Comprehensive medical and dental assessments, including patient history, radiographs, and CT scans, are required to:
 - Assess bone volume and density
 - Identify critical anatomical structures (e.g., mandibular nerve, maxillary sinuses, adjacent teeth)
- Consult the patient's physician if they are undergoing steroid therapy, anticoagulation, bisphosphonate use, or chemotherapy, as these may impair healing.

- **Implant Angulation and Placement**

- Improper angulation or placement may lead to complex restorations, overloading, or implant failure.
- Utilize diagnostic tools (e.g., x-rays, surgical guides) to ensure correct angulation and avoid critical structures.

- **Sterility**

- Use only sterile components with intact packaging.
- Do not use the system if the sterile barrier is compromised.
- Sterilize non-sterile components according to manufacturer guidelines.

- **Insertion Torque**
 - Exceeding recommended insertion torque may cause bone necrosis or component fractures.
 - Follow recommended torque values to prevent premature loosening or mechanical failure.
- **Electrosurgery Precaution**
 - Avoid using electrosurgery near implants to prevent heat-related tissue and bone damage.
- **MRI Safety**
 - Always notify health care providers and imaging technicians that you have dental implants before magnetic resonance imaging (MRI) or X-ray procedures, Dental implants can distort or interfere with these images.
 - The FDA is not aware of any adverse events reported for MRI or X-ray with dental implants.
- **Drilling and Nerve Safety**
 - Take precautions during drilling to avoid damaging nerves and blood vessels.
 - Incorrect drill depth may result in permanent nerve injury or hemorrhage in the floor of the mouth.
- **Implant Failure Indicators**
 - Monitor for implant failure signs:
 - Excessive mobility
 - Peri-implant bone loss exceeding 50%
 - Radiographic alterations
 - Remove failing implants promptly and allow atraumatic site healing.
- **Component Compatibility**
 - Use only DUAL bone drills and prosthetic components with DUAL Implant.
 - The use of third-party components may cause incompatibility, fractures, or failure.
 - The manufacturer disclaims liability for failures due to non-compatible components.
- **Small Diameter and Short Implants**
 - Small diameter implants and angled abutments are not recommended in the posterior due to high occlusal forces.
 - Implant Platform Size for Mini implants (3.3 mm Diameter): Only in lower Anterior incisors
 - Short implants require monitoring for peri-implant bone loss, mobility, and radiographic changes.
 - Consider two-stage surgery, implant splinting, wider fixtures, and extended healing times.
- **Overloading and Fracture Risks**
 - Implant or abutment failure may occur due to improper occlusion, excessive forces, metal fatigue, over-tightening, or insufficient support (e.g., cantilevered restorations).

6.2 Precautions

- **Implant Integrity**
 - Prevent contact of implants with foreign substances.
 - Avoid touching the endosseous portion.
 - Do not use implants past the expiration date or if detached from their holder inside the vial.

- **Implant Success**

- A 100% success rate is not guaranteed.
- Failure to follow surgical protocols or post-operative care may result in implant failure.
- Treatment may lead to bone loss or biological and mechanical complications (e.g., implant fatigue fractures).

- **Team Cooperation**

- Successful treatment requires collaboration between the surgeon, restorative dentist, and laboratory technician.

- **Before Surgery**

- Perform thorough clinical and radiological evaluations.
- Exercise caution with patients at risk of impaired healing (e.g., smokers, poor oral hygiene, uncontrolled diabetes, previous radiotherapy, infections, bisphosphonate therapy).
- Preoperative hard and soft tissue deficiencies may compromise aesthetic outcomes.

- **At Surgery**

- Ensure surgical instruments are in good condition.
- Evaluate bone quality and primary stability to select appropriate loading protocols.
- Avoid damage to nerves, blood vessels, and adjacent structures.

- **After Surgery**

- Provide clear postoperative care instructions focusing on oral hygiene.
- Schedule regular follow-ups to monitor healing, implant stability, and treatment outcomes.

6.3 Breakage

- **Implant and Abutment Fractures**

- Fractures can occur if loads exceed design limits.

- **Contributing Factors**

- Bone loss reducing implant support
- Insufficient implant number, size, or placement
- Prosthetic design flaws, such as excessive cantilevering or incomplete abutment seating
- Angulations exceeding 30 degrees
- Occlusal interferences and parafunctional habits (e.g., bruxism, clenching)
- Improper prosthesis fabrication or trauma

- **Preventive Measures**

- Address risk factors during treatment planning
- Optimize implant number and size, minimize cantilever lengths, adjust prosthetic design, and manage parafunctional habits (e.g., with night guards)

6.4 Changes in Performance

- Patients must be informed about contraindications, side effects, and precautions.
- If implant performance changes (e.g., prosthesis looseness, infection, persistent pain, or other symptoms), they must seek immediate professional care.

- Prompt intervention is critical for implant longevity and success.

6.5 Risks Associated with Dental Implant Systems

- Damage to surrounding natural teeth during implant placement
- Injury to the surrounding tissues during surgery, such as sinus perforation
- Injury during surgery (for example, fracture of surrounding jawbone)
- Inadequate function, such as feeling like the teeth do not bite together normally
- A sensation that the tooth is loose or twisting in place resulting from an abutment screw loosening
- Implant body failure (looseness of the implant body)
 - due to systemic infection, which may be more likely in patients with uncontrolled diabetes
 - due to local infection in bone and gums supporting the implant body
 - due to delayed healing, which may be more likely in patients who smoke
- Difficulty cleaning the gums around the implant, resulting in poor oral hygiene
- Untreated periodontal disease
- Post-surgical numbness due to nerve impingement or damage

7. Cleaning And Disinfection

DUAL Implants

- **Model A & B (Single-Piece and Two-Piece):**
Delivered sterile and intended for single use only.
Do not clean or sterilize these implants.
- **Model C & D (Abutment & Connecting Screw):**
Delivered non-sterile and intended for single use only. If cleaning is required, the recommended method is as follows:

Step-by-Step Cleaning and Disinfection for DUAL Dental Abutment & Connecting Screw

7.1. Cleaning:

- Place disassembled parts in the cleaning bath for the specified time, ensuring full coverage.
- If necessary, carefully brush parts with a soft brush.
- Prevent parts from coming into contact with one another.
- Use a dedicated ultrasonic machine with a detergent suitable for surgical instruments.
- Alternatively, clean by hand, followed by an ultrasonic bath with an appropriate detergent.

7.2. Rinsing:

- Remove parts from the cleaning bath.
- Rinse thoroughly with water **at least three times**.

7.3. Disinfection:

- Place disassembled, cleaned parts in the disinfection bath for the specified time.
- Ensure full coverage and prevent contact between instruments.
- Rinse all parts' cavities **three times** using a disposable syringe.

7.4. Final Rinsing and Drying:

- Remove parts from the disinfection bath.
- Rinse thoroughly with water **at least five times**.
- Dry instruments internally and externally using filtered compressed air.

8. Sterility

8.1 For Sterile Models

- **DUAL Implants Model A & B** (Single-Piece and Two-Piece) are delivered sterile via gamma radiation and are for **single use only**.
- **Do not re-sterilize** sterile implants, as this may compromise material properties and surface characteristics.

Handling Protocol:

- Do not open the sterile packaging until immediately prior to implant placement.
- Use **aseptic techniques** when handling and removing the implant.
- If the sterile packaging is opened, damaged, or compromised, **do not use** the implant.

8.2 For Non-Sterile Models

- **DUAL Model C & D** (Dental Abutments and Connecting Screws) are delivered **non-sterile** and must be **sterilized before use**.
- Non-sterile products must be placed in a **sterilization pouch** and sealed prior to sterilization.

Sterilization Parameters:

Use one of the following sterilization methods to achieve a **Sterility Assurance Level (SAL) of 10^{-6}** :

Cycle type	temperature	Exposure time	Dry time
Gravity (steam)	132° C 270° F	15 minutes	20 minutes
Pre-vacuum (steam)	132° C 270° F	4 minutes	20 minutes
Pre-vacuum (steam)	134° C 273° F	3 minutes	20 minutes
Pre-vacuum (steam)	134° C 273° F	18 minutes	20 minutes
Dry heat	160° C 320° F	120 minutes	N/A
Steam sterilization cycle	121° C	40 minutes	20 minutes
Steam sterilization cycle	134° C	20 minutes	20 minutes

- Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed above.
- Verify the **calibration of the sterilization unit** to ensure that temperatures and times meet requirements without exceeding limits.
- Periodically use **biological indicators** to confirm autoclave effectiveness.

8.3 Handling Guidelines

- Implants and components must be handled using **powder-free sterile gloves**.
- Avoid contact with hard objects to prevent **damage to the implant surface**.
- Store sterilized components in a **sterilization pouch** until they are ready for use.

9. Potential Side Effects and Complications of DUAL Implants

Undesirable Side Effects

The placement of dental implants is an **invasive procedure** and may involve temporary or longer-term side effects.

Temporary Symptoms:

- Pain
- Swelling
- Gingival inflammation
- Phonetic challenges (difficulty with speech)

Other Side Effects:

- Inflammation, infection, bleeding, hematoma
- Premature exposure of the cover screw during the healing period
- Bone growth over the cover screw
- Retained cement, calculus accumulation, or mucositis

Soft Tissue Issues:

- Ulcers
- Hyperplasia
- Soft and/or hard tissue recession

Functional or Mechanical Issues:

- Lip biting, bruxism, or clenching, which may impact implant success
- Phonetic alterations requiring adjustments to neighboring or opposing prostheses
- Discoloration in the mucosal area
- Gag reflex triggered during connection or removal of components in patients with a sensitive gag reflex.

10. Single-Use Only

- All **DUAL Implants** are for **single use only**. Reuse or re-sterilization is **strictly prohibited**.
- components labeled “**Single Use Only**” are designed for **one-time use** and **must not** be reused under any circumstances.
- Reuse of these devices has **not been clinically or scientifically validated**, and there is **no data** supporting their safety or performance after multiple uses.

Risks Associated with Reuse:

Reusing a single-use device that has come into contact with blood, bone, tissue, body fluids, or other contaminants may result in:

- **Transmission of infectious agents**
- **Patient injury**
- **Mechanical failure** of the device

11. Product Packaging

- All **DUAL Implants** are **cleaned, packaged, and sterilized** within an **environmentally controlled clean room** to ensure safety and readiness for immediate clinical use.
- Each implant is suspended on a **carrier / holder**, allowing for secure transfer to the surgical site while minimizing the risk of contact contamination.
- Both the **implant** and the **inner vial/carrier packaging** are delivered in a **sterile condition**.

Packaging Integrity:

- Prior to use, **inspect all packaging** for visible damage or signs of tampering.
- If the sterile packaging is **compromised, do not use** the product. Discard and replace with a new, sterile implant.

Manufacturer Responsibility:

- **TITAN INDUSTRIES** assumes **no responsibility** for implants that have been:
 - **Re-sterilized**
 - **Reused**
 - **Cleaned or altered** by third parties

Recommendation:

- Always maintain a **backup implant** on hand to avoid procedural delays in the event of packaging compromise.

12. Traceability

- For regulatory compliance and patient safety, the following information must be **recorded in the patient's chart**:
 - Implant **product description**
 - **Lot number**
 - **Product traceability labels**
- The **inner vial label** includes a **lot number**, which must be documented in the patient file to ensure full traceability of the implant.
- The **outer packaging label** also contains a **lot number**, which should be recorded alongside the product description in the patient's medical record.

13. Shelf Life & storage condition

- The **product expiration date** is indicated on the label by the **hourglass symbol** (⌚), followed by the **year and month** of expiration.
- **DUAL Implant Systems** are considered **sterile for 5 years** from the date of sterilization, **provided that the packaging remains intact**.
- Adhering to these guidelines helps preserve **product sterility and performance**, thereby **reducing the risk of complications** and ensuring **patient safety**.

Important Notes:

- **Always verify** the expiration date on the product label **prior to use**.
- **Do not use** any product that:
 - It has **exceeded its expiration date**.
 - **Shows signs of compromised packaging**.

Storage Condition:

- Store the product in a **dry place**, inside its **original packaging**, at a temperature **not exceeding 30°C** ,**Avoid direct exposure to sunlight**.
- **Incorrect storage** may alter device characteristics and **lead to failure**.

14. Disposal

- **Disposal of the device** must comply with **local regulations** and **environmental requirements**, taking into consideration the **level of contamination**.
- All **used implants and instruments** are considered a **potential biohazard**, as they may be contaminated with:
 - Blood
 - Body fluids
 - Bone
 - Soft or hard tissue
- Handle and dispose of these products in accordance with:
 - **Accepted medical practice**
 - **Local, state, and national laws and regulations**

15. Disclaimer

- This document is intended **exclusively for licensed physicians** and is **not meant for lay persons**.
- The information provided is of a **general nature** and does **not constitute**:
 - Medical advice
 - Recommendations
 - Therapeutic statements

- This document **does not replace** individual **patient evaluation** or **tailored medical guidance**. Each patient must be assessed by a **qualified healthcare professional**.

16. Liability

Manufacturer and Distributor Responsibility

Titan Industries and its distributors are **not liable** for complications, injuries, implant failures, or adverse effects resulting from:

1. Incorrect indications or surgical techniques
2. Improper material selection or handling
3. Use of expired products
4. Inadequate aseptic conditions
5. Patient anatomy or implant overloading
6. Non-adherence to the recommended guidelines

Surgeon's Responsibility

The operating surgeon bears **full responsibility** for:

- Complications or consequences arising from the procedure
- Providing appropriate **patient education** regarding the function, care, and risks of implants
- Using the product in **strict accordance** with the provided **Instructions for Use (IFU)**

Product Suitability

- It is the **user's responsibility** to determine the **suitability** of the product for each specific patient or procedure.
- Titan Industries disclaims liability** for:
 - Errors in professional judgment or clinical practice
 - Misuse or **off-label** use of its products
 - Any **direct or indirect damages** resulting from improper use

Updates and Regulatory Information

Product Updates

- Users must **regularly consult the manufacturer's website**:
<https://www.dualimplant.com/>
 to stay informed about **updates**, safety communications, and **clinical recommendations**.
- DUAL Implants must be used **exclusively with original DUAL components and instruments** to ensure compatibility and safety.

17. e-Labeling

Electronic Instructions for Use (IFU)

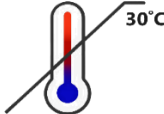
- Instructions for Use (IFU) are available in **electronic format** on the manufacturer's website.
→ <https://www.dualimplant.com/ifu>
- Visit the site to access the **most up-to-date version** of the document.

Paper Copy Requests

To request a **paper copy** of the IFU, you may:

- Email** the address provided on the product label.
- Alternatively**, contact the manufacturer via the **phone number listed** on the official website.
- Further instructions** for obtaining the IFU will be provided upon request.

18. Symbols

	The device is a Medical Device.
	Batch Code/ lot number
	Catalogue number / Reference number
	Use by date / Expiry date
	Temperature limit (not more than 30°C)
	Sterilized by Gammma radiation.



Single sterile barrier system with protective packaging outside



Single sterile barrier system with protective packaging inside



Non sterile



Do not use if package is damaged.



Do not re-use



Caution: Federal law restricts the sale of this device to a licensed dentist.



Iso certificate 13485



Manufacturer



GTIN Code



Electronic instructions for use