



**DYNAMIC  
ABUTMENT®  
SOLUTIONS**

**TiBase® and Screws  
General instructions for use**



**Data of Manufacture Company:**

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**Note:** For any contradictions in the translations of this document, the prevailing language is Spanish

**Symbols**

	CE Marking 0051		Batch Code
	CE Marking		Material
	Consult instructions of use		Manufacturer
	Not reuse		Do not use if the package is damaged
	Reference Code of the product		Non-sterile
	Place out of direct sunlight		American Federal Law restricts the sale of this device to dental professionals or at the order of the same.
	Quantity		

**1. PRODUCT PRESENTATION**

All Talladium products are supplied as non-sterile in a heat-sealed blister pack which, as a safety seal, ensures the product is untouched since being packaged. The product packaging is labelled (UNE-EN ISO 15223-1:2017). Each package contains a single device.

**2. DESCRIPTION & INTENDED USE: Product types**

**1) Screws**

**Description:** Manufactured device connecting directly to a prosthetic attachment or restoration.

**Intended use:** (1) mounting the attachments and/or prosthesis to implant replicas/analogue on the prosthetic working model; (2) permanent clamping of the attachments and/or prosthesis to the implants in the clinic, following sterilisation (see Point Cleaning & Sterilisation).

**Labelling:** The description on the label provides information on:

- Metrics (M)
- Total length (L in mm)
- Maximum tightening torque (given in N.cm)
- Connection to the screw head

**Variants:**

- **Dynamic Screws:** Screw that is suitable for milled structures which may or may not require angulation in the screw entry channel. To work correctly, only use with a 'Dynamic screwdriver', which enables angled bolting and prevents screw crowning.
- **Screw or straight screw:** Screw that is suitable for milled structures not requiring angulation in the screw entry channel. Precaution for screws or straight screws: A suitable screwdriver should be used (based on the screw head connection type) to ensure correct bolting, preventing screw crowning.

**Material:** Grade 5 Titanium alloy (Ti 6-Al 4-V) per ASTM international standards F136-12 and ISO 5832-3.

**2) TiBase®:**

**Description:** Metallic attachment with connection made to connect to the complementary implant/analogue. There are various compatible variants available with different connections (see compatibilities in the catalogue).

**Intended use:** Provide support for the prosthetic restoration; intended to replace dental parts to restore proper mastication.

**Labelling:** The description on the label provides information on:

- identification: Engaging / Non-Engaging
- value of gingival height (G given in mm)
- value of cemented height (HC given in mm), exclusive to the 3Ti-base.
- compatibility code (Comp. 0000)

**Variants:**

- **Dynamic TiBase®:** TiBase® type suitable for milled structures requiring angulation in the screw entry channel. This type can also be used in structures without canal angulation.
- **Straight TiBase®:** TiBase® type suitable for milled structures not requiring angulation in the screw entry channel.
- **Non-rotating TiBase®:** Suitable attachment in production of bridges, bars & multi-structures.
- **Rotating TiBase®:** Suitable attachment in production of individual structures.
- **3TiBase®:** Attachment with a 9mm cemented surface designed specifically for cases requiring a larger support surface to achieve a stronger, more resistant structure. Available in Non-Engaging (ideal for producing several structures) and Engaging (ideal for producing individual structures) formats. Material: Anodized Grade 5 Titanium alloy (Ti 6-Al 4-V) per ASTM international standards F136-12 and ISO 5832-3.
- **Gingival height (G):** There are a number of variants with different gingival heights depending on the type of TiBase® chosen. The TiBases® with greater gingival heights facilitate work where the gingival margins are uneven.

**3) Scanbody extraoral**

**Description:** Plastic device that attaches and adapts perfectly to the TiBase® without rotation.

**Intended use:** Attaches to the TiBase® to identify the position and orientation of the dental implant (or similar) when scanning.

**Labelling:** The description on the label provides information on:

- **Type:** code identifying the TiBase® group with which it should be used. The part is identified by laser-engraving on its side.

**Material:** PEEKTM CLASSIX - biocompatible thermoplastic polymer specifically suited for healthcare use.

**4) Screwdriver**

**Description:** Tool or support instrument for handling and bolting the TiBase®-screw-implant (or analogue) system.

**Intended use:** To assemble and/or position the TiBase®-screw-implant (or analogue) system. Intended for continuous use over a short period of time (less than 60 mins).

**Labelling:** The description on the label provides information on:

- Head type
- Total length

**Variants:**

- **Dynamic Screwdriver:** Tool for the handling of and thread dynamic screws.
- **Screwdriver:** Tool for the handling of and thread screws or straight screws.

**Materials:** Stainless steel.

**3. INDICATIONS:**

The TiBase® and screw system comprises prefabricated prosthetic components, which connect directly onto the endosseous dental implant; designed to be used in prosthetic restoration.

**4. CONTRAINDICATIONS:**

Titanium attachments are contraindicated for patients who are allergic or hypersensitivity to the Titanium Ti 6-Al 4-V alloy.

**5. WARNINGS**

Talladium España S.L implant products can only be used by dental professionals familiar with the maxillary implant field and its specialities, e.g. planning and diagnostics, surgery, dentistry, and prosthetic technique.

The system components facilitate the clinical and laboratory work. Clinical staff are responsible for using each product as stated in the instructions and deciding if the product is suitable for the specific patient situation to obtain the best results

Products labelled for single use cannot be reused. This is to avoid loss of functionality and risk of cross-infection between patients. Talladium España S.L. accepts no responsibility for any attempt to reuse the same.

**6. PRECAUTIONS**

Consult use restrictions on the label. Pay attention to the measurements, threading phases and dimensions of the product used, as the proper combination of components depends on the choices made. Ensure the different screw threading comprising the system catalogue are correct and pay attention to the attachment-implant and screw-screwdriver connecting parts.

If the protective packaging is broken, we recommend returning the product for replacement.

**Using the screws:**

Do not use the same screw in the laboratory (production process) and the clinic (fixing the prosthesis in the patient's mouth). Do not use screws without their original sealed packaging when fixing the prosthesis in place.

Titanium, like any other metal subject to constant loads, suffers fatigue and its mechanical resistance decreases. For a good mechanical operation of the prosthesis on the implant, the anchoring system must be secured; thus, should any type of wear or defect be detected in the screw, this should be replaced.

Screws placed in the mouth must be aligned with the axis of the implant.

**Specific TiBase® precaution:**

Do not use a narrow-platform TiBase® for posterior restorations (molars and premolars) as the system may fail.

**Additional precautions for the clinical procedure:**

The products must be safely attached to prevent aspiration during intraoral use.

With immediate loads derived from recently inserted implants, the bolted components must be handled with all due care and manually with all due care, waiting for osteo-integration before applying torque.

Special care needs to be taken when threading the attachments which hold the unitary reconstructions in place to avoid unnecessary tension on the implant inserted into the bone. The site may become obstructed following the operation or due to scarring. Thus, it needs to be checked and cleaned to ensure they work properly. Ensure the prosthesis is correctly inserted by means of an x-ray, focusing on the head of the connection, at an angle of 90 degrees from the axis.

The shelf-life of reusable products depends on various factors, including method and duration of each use and handling between uses. Thus, a close inspection and operational tests are needed prior to reusing them. If instruments are found to have oxidised surfaces, dispose of them. Even the slightest corrosion means the instruments are no longer biocompatible.

## 7. OPERATIONAL USAGE:

**In the laboratory:**

a) Before inserting any attachments, ensure all components are clean and undamaged. Check that all the components are compatible.

b) Place the TiBase® on the replica implant, present on the working model. The TiBase® cut is the equivalent of the screw entry in the future prosthesis, so position the TiBase® according to the required position of the angled hole. Fix in place with a suitable screw. Full torque is not required; tighten the screw a little to ensure the TiBase® is held in position, as required.

c) Couple the scanbody to the TiBase®. The outer lengthwise scanbody cut corresponds to the opposite side of the TiBase® cut and adapts to it, achieving a single coupling point.

d) Talladium España S.L scanbodies are reusable, so the scanbody needs to be checked to ensure it is seated on the TiBase® with no gaps or sideways movements. Continued use may lead to internal wearing of the geometry. Should these problems be detected, replace the scanbody with a new one.

e) It is generally recommended to work with a removable gum shield to ensure the TiBase® and scanbody are correctly positioned.

f) Once the TiBase® and scanbody are in position, start scanning. Digitally design the prosthesis using the CAD library of the DAS corresponding to the compatibility of the TiBase® used. Ensure the compatibility number indicated is chosen (see the compatibility number in 'Extraoral Library Codes', included with the CAD library; also available at: [www.dynamicabutment.com](http://www.dynamicabutment.com)). A poor choice in terms of compatibility will lead to incorrectly done work, given the variability in the parameters in each of these compatibilities. Talladium España S.L accepts no liability for a poor choice in compatibility from the library.

**Beware:** For 3TiBase®, follow the preceding steps with the standard TiBase® for this connection and the compatible scanbody. Once scanned and with the digital model prior to milling completed, replace the standard TiBase® from the scan with the 3TiBase. Cut the 3TiBase® to 7 mm (or 5 mm where necessary) using a cutting disc. Polish the cut area using rubber to prevent any ridges or edges forming. Ensure the correct height is selected from the library based on the cut made.

**Beware:** The straight TiBase® is designed to scan using the Dynamic µScanbody system from Talladium España S.L.

**Note:** Check the CAD library user guide at: [www.dynamicabutment.com](http://www.dynamicabutment.com). Instructions on how to use the Dynamic µScanbody system are available at: [www.das-eifu.com](http://www.das-eifu.com). Feel free to contact Talladium España S.L. to ask for a free hard copy of the IFUs you require. You will receive the document within 5 working days. Remember that Talladium España S.L. has a Customer Service Hotline (Tel. +34 973 289580) for queries and CAD software library installations.

**In the clinic:**

a) The products are supplied as NON-sterile. Therefore, they should be cleaned, disinfected and sterilised prior to intraoral use (see section Cleaning and Sterilisation).

b) Remove the temporary restoration, where applicable.

c) Always consult the user manual from the manufacturer of the original implants.

d) Insert the fixed prosthesis and tighten the prosthetic screws to the recommended torque. Warning: Excess torque may crack or damage the screw.

e) Close the screw access channels.

## 8. CLEANING AND STERILISATION

The products are supplied as NON-sterile. Therefore, they should be cleaned, disinfected and sterilised prior to being used in the mouth.

Remove the product from its packaging and start to clean and disinfect, preferably in an ultrasonic bath with a cleaning and disinfecting solution normally used with medical devices.

Always handle with powder-free gloves.

Recommended sterilisation method: damp heat in an autoclave, applying a standard 121°C cycle for 15 minutes (as per UNE ISO 17665-1: 2007).

All surgical instruments must be sterilised prior to use. Prevent any risk of contamination by ensuring the product does not come into contact with non-sterile objects.

## 9. TRACEABILITY

A card for the patient is supplied with the system, together with the various labels to identify the dental position in which the system has been inserted. This information should be registered in the patient's chart to avoid future problems. This ensures correct choices made in future repositioning and awareness of the compatible instruments

required by the healthcare professionals.

## 10. MAGNETIC RESONANCE (MR) SAFETY INFORMATION

The system has not been assessed in terms of safety and compatibility with magnetic resonance (MR) environments. No heating, displacement or image interference tests have been performed for MR environments.

## 11. STORAGE

The product should be kept in its original packaging in a dry place at room temperature, e.g. 18 to 25°C, away from direct sunlight.

## 12. ELIMINATION

Once the shelf life of a Talladium España S.L product has been reached, it should be processed in accordance with the legislation and standards of the appropriate authority, under environmental requirements and considering all relevant levels of contamination

**Warning:** Inform the manufacturer, Talladium España S.L., and the relevant authority of any serious incident related to the product.