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DYNAMIC ABUTMENT® SOLUTIONS

TiBase® and Screws
Instructions for use

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

1. PRODUCT PRESENTATION

All Talladium España S.L. products are supplied as non-sterile in a heat-sealed pack containing a single device, ensuring the product is untouched since being packaged.

2. DESCRIPTION & INTENDED USE

PRODUCT TYPES

1) Screws CE 0051

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
- AX: Anodized Dynamic screw (each number corresponds to a type of anodized, for example, A1: Anodized 1).

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 international standards ASTM F136-13 and ISO 5832-3.

2) TiBase® CE 0051

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 international standards ASTM F136-13 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.

Material: Grade 5 Titanium alloy (Ti 6-Al 4-V) per international standards ASTM F136-13 and ISO 5832-3, with anodised surface.

3) Scanbody extraoral CE

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 CE

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 hypersensitive 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). 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. Instructions on how to use the Dynamic µScanbody system are available at: www.das-eifu.com. Feel free to contact Taladium 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 121ºC cycle for 15 minutes (as per UNE ISO 17665-1).
For the USA: sterilize in a pre-vacuum autoclave at 132 °C for 4 minutes and leave to dry for at least 30 minutes. Sterilization autoclaves and accessories authorised by the FDA for the recommended sterilization parameters, pursuant to the AAMI ST79 standard, must be used.
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

On the bottom half of the accompanying label there are 3 tabs containing information on device traceability. These extra labels can be removed and added to the patient card or patient file (clinic & laboratory). This information needs to be recorded to avoid future mishaps and ensure stock is correctly resupplied, in addition to providing knowledge of all compatible instruments/tools required by the medical professional.

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 25ºC, 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.

SYMBOLS LEGEND

CE 0051	CE Marking 0051	LOT	Batch number
CE	CE Marking	MAT	Material
	Consult instructions for use		Manufacturer
	Do not reuse		Do not use if package is damaged
REF	Catalogue number	NON STERILE	Non-sterile
	Keep away from sunlight		Date of manufacture
Qty	Quantity	Rx Only	American Federal Law restricts the sale of this device to dental professionals or at the order of the same.