Ed. 2020-02
ABUTMNT_2002_EN
LAST REVIEW: 2020/07/17

DYNAMIC ABUTMENT® SOLUTIONS

Straight & Dynamic Abutments
Instructions for use

Data of Manufacture Company:
Talladium España, S.L
C/Virginia Woolf, 17
25005 Lleida - España

Technical Support and Customer Service:
(+34) 973289580
www.dynamicabutment.com
www.dynamicabutment.es

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 AND INTENDED USE

PRODUCT TYPES

1) Screws CE 0051

Description: Device used to clamp attachments and/or prostheses to the dental implant. It comprises a head with a machined connection to fit the complementary screwdriver and threading of a specific diameter to allow the dental implant or analogue to screw into place.

Intended use: (1) Mounting the attachments and/or prosthesis to implant replicas on the prosthetic working model; (2) Permanent clamping of the attachments and/or prosthesis to the implants in the clinic, following sterilisation (see: 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 Screw: Suitable for milled structures requiring angulation in the screw entry channel. Precaution for dynamic screws: To work correctly, only use with a 'Dynamic screwdriver', which enables angled bolting and prevents screw crowning.
• Straight-Screw: Suitable for milled structures not requiring angulation in the screw entry channel. Precaution for uni-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 e ISO 5832-3.

2) Abutments **metallic** CE 0051 **castable** CE

Description: Attachment with connection made to connect to the implant or similar. There are various compatible variants available with different implant connections (see compatibilities in the catalogue).

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

Labelling: The description on the label provides information on:
• identification: rotatory/non-rotatory
• material for the base
• maximum angulation value (exclusive to Dynamic Abutments)
• compatibility code (Comp.0000)

Variants:
• Straight-Abutments: Attachment comprising 1-2 parts: there is a single plastic structure for castable abutments, while metallic abutments have a connected castable cap. Suitable to produce structure not requiring an angled screw entry channel.
• Dynamic Abutments: Attachment comprising 2 parts - base and cap - which are connected by means of an elbow, for articulation, enabling the cap to pivot on the semi-spherical base. There are fully castable attachments (base + cap) and other abutments with metallic bases and a connected castable cap. This attachment is suitable for producing structures which need screw entry channel correction.

Both abutment types are available in rotatory (suited to bridges, bars and multi-structures) and non-rotatory formats (suited to single structures). Consult the catalogue for available compatibilities.

Material: Available in different materials (see material on product label). There are castable abutments made of POM and metallic abutments with a machined Cobalt-Chrome or Tilite base with the cap in POM. The Tilite alloys contain 62-76% medically pure Nickel.

3) Converters CE 0051

Description: A device with a connection for the dental implant and for the attachment which clamps the prosthetic restoration.

Intended use: Transform the dental implant internal connection into an external one.
Labelling: The description on the label provides information on:
• Metrics (M)
• Maximum tightening torque (given in N•cm)
• Compatibility code (Comp. 0000)

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

4) Screwdriver CE

Description: Tool or support instrument for handling and bolting the abutment-screw-implant/analogue system.

Intended use: Enable the application of torque to the screw to position the abutment-screw-implant/analogue system and/or facilitate unscrewing of the same.

Labelling: The description on the label provides information on:
• Head type
• Total length

Variants:
• Dynamic Screwdriver: Tool to manoeuvre and thread dynamic screws.
• Screwdriver: Tool to manoeuvre and thread uni-screws.
• Screwdriver for converter: Tool to manoeuvre and thread converters.

Material: Stainless steel

5) Analog CE

Description: Device with a machined connection which replicates the dental implant connection.

Intended use: Simulates the dental implant connection and positioning in prosthetic models.

Labelling: The description on the label provides information on:
• compatibility code (Comp.0000)

Material: Stainless steel

6) Protective cylinder CE

Description: Protective plastic cylinder for the abutment.

Intended use: Keep the screw access chennel free of impurities during the closing-up process.

Labelling: The description on the label provides information on:
• Ø of the cylinder (in mm)

Material: POM

3. INDICATIONS

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

4. CONTRAINDICATIONS

The attachments are contra-indicated for patients who are allergic or hyper-sensitive to the corresponding materials (see materials in the Description and Intended Use section).

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). When fixing the prosthesis in place, do not use screws which are not in their original sealed packaging.

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 precaution for abutments:

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

Additional precautions for the laboratory procedure:

The protective cylinder cannot be melted.

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 need to be manoeuvred 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 be obstructed after the operation or healing process and, consequently, should be checked and cleaned. 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 patient should be monitored after the implant treatment and informed of the recommended oral hygiene procedures.

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 be worn or have oxidised surfiaces, 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 abutment on the replica implant, present on the working model, and fix it in place using the screw. It must be attached to the model, meaning the prescribed torque is not necessary. Ensure the site is correct.
With Dynamic Abutments, the cap enables movement to adjust the screw entry channel where necessary. Note: Maximum angulation can only be achieved in the milled area of the cap.

c) Trim the cap to the height required for reconstruction. Use the protective cylinder to close up the structure; put it into the cap to keep the inside clean and impurity-free.

d) Take into consideration the shape of the patient's mouth when starting to close up the structure; follow the conventional procedure, then remove the protective cylinder.

e) Once the structure is closed up, insert the necessary sprues and vents to ensure the metal can enter comfortably.

f) Stick the wax structure with the sprues to the base of the cast cylinder.

g) Use a debubblizer on the wax.

h) Place the cast cylinder on the base and pour on the specific coating until the structure is covered.

i) Once the coating has set, place the cylinder in the kiln and preheat to the desired temperature (this depends on the metal used to cast).

j) Follow the manufacturer's instructions for the casting procedure. The metal used in the casting will depend on the machined base of the prosthetic abutments (Tilite or Co-Cr); for fully castable abutments, the choice of metals is open.

k) Remove the coating and check the casting has been done correctly. Cut the sprues. Adjust and check the structure.

l) Then, apply the aesthetic coating.

m) Buff and clean the restoration before sending it to the dentist.

Note: Instructions on how to use the system are available at: www.das-eifu.com. Remember that Talladium España S.L. has a Customer Service helpline (Tel. +34 973 289 580) for any queries.

In the clinic:
a) The products are supplied as NON-sterile. Therefore, they should be cleaned, disinfected and sterilised prior to intraoral use (see: 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 up 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-EN ISO 17665-1.

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 abutment-screw system has not been assessed in terms of safety and compatibility with magnetic resonance (MR) environments. No heating, displacement or 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, i.e. 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		Date of manufacture
	Consult instructions for use		Manufacturer
	Do not reuse		Do not use if package is damaged
REF	Catalogue number	NON STERILE	Non-sterile
Qty	Quantity	Rx Only	American Federal Law restricts the sale of this device to dental professionals or at the order of the same.