



DYNAMIC SCREWDRIVER

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

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 PURPOSE

Dynamic Screwdriver

Description: Tool or implement that helps manipulate dynamic screws.

Intended purpose: To apply the tightening torque and/or unscrew the dynamic screw.

Labelling: The description on the label provides information on:

- Total length
- Maximum angle

Variants: Dynamic screwdrivers are available in 3 different lengths depending on user needs (L=18 mm; L=24 mm; L=32 mm).

Materials: Stainless steel

3. PATIENT TARGET GROUP OR GROUPS

The device is intended for use in fully or partially edentulous patients.

Talladium España S.L. implantology products may only be used by dental professionals familiar with the field of maxillary implantology and prosthodontics.

4. INDICATIONS

The dynamic screwdriver is designed to apply the tightening torque to and/or unscrew the Dynamic System 3.0 screw from attachments and/or prostheses with the screw entry channel at 0° to 30°.

5. CONTRAINDICATIONS

No specific contraindications for this product.

6. WARNINGS

The system components facilitate the clinical and laboratory work. Thus, the instructions for use need to be read carefully for the best possible results.

7. PRECAUTIONS

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

The shelf-life of reusable products depends on various factors, including method and duration of each use and handling between uses. It has been shown that the screwdriver can be reused up to 100 times under normal conditions and when following the specifications detailed in the instructions for use. However, close inspection and operational tests are needed prior to reusing it. If instruments are found to be worn or have oxidised surfaces, dispose of them. Even the slightest corrosion means the instruments are no longer biocompatible.

Dynamic screwdrivers have an in-built system that detects the use of excess torque and prevents the screw being stripped or broken. This system deforms the screwdriver before any damage can occur (see illustration 1). It is important to check the grooving in the screwdriver head prior to usage to ensure the device is in good condition. If any deformation is found, change the screwdriver.

Dynamic screwdrivers must be used exclusively with compatible manual handle.

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.

8. OPERATIONAL USAGE

a) Check component compatibility prior to use, bearing in mind that the dynamic screwdriver must only be used with Dynamic System 3.0 screws.

b) Check the state of the grooves in the head of the screwdriver. Do not use it if there is any deformation.

c) Examine the condition of the screwdriver connection. Do not use it if there are signs of wear.

d) Clean, disinfect and sterilise the device prior to intra-oral use (See Cleaning & Sterilisation).

e) The labelling for the screw details the maximum permitted torque. Warning: Excess torque may crack or damage the screw.

Note: Remember that Talladium España S.L. has a Customer Service helpline (Tel. +34 973 289 580) for any queries.

9. 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. If the product is being reused, make sure to clean it very carefully. Using a suitable brush, scrub the screwdriver until all visible dirt and residue is removed and then put it into the ultrasonic cleaner with a cleaning solution and disinfectant.

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-EN ISO 17665-1.

For USA: sterilize in a pre-vacuum autoclave at 132°C for 4 minutes with a minimum drying time of 30 minutes. FDA cleared autoclaves and sterilization accessories should be used for the recommended sterilization parameters in accordance with AAMI ST79.

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. Sterilised products may not be stored as this could compromise their condition.

10. 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.

11. STORAGE

The product must be kept in a dry place at room temperature and out of direct sunlight.

12. ELIMINATION

Talladium España S.L. products, once their useful life is over, may contain potentially infectious human biological remains, therefore, they must be correctly disposed of according to the legislation, methods and standards of the competent authority for this type of products.

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

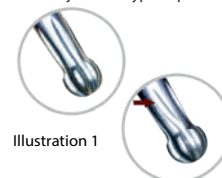

















Illustration 1

SYMBOLS LEGEND

	CE Marking		Manufacturer
	Consult instructions for use		Date of manufacture
	Catalogue number		Quantity
	Batch number		Do not use if package is damaged
	Non-sterile		Distributor
	American Federal Law restricts the sale of this device to dental professionals or at the order of the same.		Medical device
	UDI as AIDC format		Keep the packaging in a dry place
	Keep out of direct sunlight		