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DYNAMIC ABUTMENT® SOLUTIONS

MINI SCANBODY AND SCREWED SCANBODY

Instructions for use

Data of Manufacture Company:
Talladium España, S.L.
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25005 Lleida - España.

Technical Support and Customer Service:
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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

1. Mini Scanbody and Screwed Scanbody CE

Description: A plastic device with a machined connection to link to the dental implant or analogue and comes with a screw to fix it in place.

Intended purpose: Attaches to the dental implant or analogue to identify the position and orientation of the dental implant when scanning.

Labelling: The description on the label provides information on:
• Connection to the screw head (in the case of the Mini Scanbody)
• Compatibility code (Comp. 0000)
• Maximum tightening torque (given in N•cm)

Etching: The Mini Scanbody has the compatibility code identification engraved while the Screwed Scanbody has the implant diameter engraved. Both have the Talladium España S.L. identification symbol.

Material: Scanbody made from PEEKTM CLASSIX, biocompatible thermoplastic polymer, specially designed for healthcare use. Retaining screw made from grade 5 Titanium alloy (Ti 6-Al 4-V) per international standards ASTM F136-13 and ISO 5832-3.

3. PATIENT TARGET GROUP OR GROUPS

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

The products for implantology of Talladium España S.L. can only be used by dental professionals familiar with the field of maxillary implantology and all its specialities, such as planning and diagnostics, surgery, dentistry and prosthetic technique.

4. INDICATIONS

The Scanbodies are designed to be used in intraoral and extraoral scanning processes when creating dental protheses.

5. 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).

6. WARNINGS

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.

7. PRECAUTIONS

Consult use restrictions on the label. Pay attention to the connecting elements between attachment-implant and screw-screwdriver.

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

Scanbodies must be exclusively used with the implant or compatible implant analog, otherwise the device may be damaged and/or scan results may prove incorrect. In the worst of cases, the implant may be damaged.

Only the fixing screw supplied with the device must be used to fix the Scanbodies. Use the corresponding screwdriver to manipulate, position and thread the screw in the implant to ensure the device is correctly fixed in place and prevent it detaching in the patient's mouth.

Additional precautions for the clinical procedure

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

The products must be safely attached to prevent aspiration during intraoral use. Check the screw and screwdriver fit together properly before using them.

8. OPERATIONAL USAGE

Clinical use:

a) Check component compatibility prior to use. Scanbodies should only be used with the corresponding implant. The device has its compatibility code engraved (in the case of the Mini Scanbody) or the implant diameter (in the case of the Screwed Scanbody) to facilitate identification. The screw should be threaded using a compatible screwdriver. The screw connection is detailed on the product label to help identification.

b) The implant connection area may be obstructed following the operation or healing process, meaning it needs to be checked and cleaned prior to putting the Scanbody in position.

c) Place the Scanbody on the implant. Should angled correction be required, bear in mind that the lengthwise slit along the Scanbody corresponds to the opposite side to where the angled channel will be.

d) Once correctly positioned, attach the Scanbody to the implant by applying the stated torque (5N•cm) using a compatible screwdriver. Warning: Excess torque may crack or damage the screw.

e) Using a dental mirror, check there are no spaces/gaps between the base of the Scanbody and the surface of the implant. If there are any, then reposition the Scanbody.

f) Proceed to the scan:

• When using the Mini Scanbody for the digital design of the prosthesis, the DAS CAD library corresponding to the compatibility of that particular Mini Scanbody must be used. Please ensure the provided compatibility number is selected (check the compatibility number in the MiniScanbody Library Codes document sent together with the CAD library, also available at www.dynamicabutment.com).
• When using the Screwed Scanbody for the digital design of the prosthesis, the OSTEOCARE_DAS CAD library corresponding to the compatibility of that particular Screwed Scanbody must be used. Please ensure the implant diameter is selected according to its compatibility (check the diameter in the engraving on the device itself).

Note: Remember that Talladium S.L. has a Customer Service Hotline (Tel. +34 973 289580) for queries and CAD software library installations.

Laboratory use:
Scanbodies may also be used in traditional extraoral procedures. Its use offers several choices in the creation of the final prosthesis. Points a), c), d), e) and f) of the protocol for clinical use must be followed for a correct scan, taking into consideration that the ScanBody must be positioned on the corresponding implant analog or replica.

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.

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

Always handle with powder-free gloves.

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.

SYMBOLS LEGEND

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