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DYNAMIC ABUTMENT® SOLUTIONS

MULTI-UNIT DAS SYSTEM
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 delivered non-sterile in a heat-sealed package containing a single device, thus ensuring that the product has not been tampered with after it was packaged.

2. DESCRIPTION AND INTENDED USE

PRODUCT TYPES

1) Straight Multi-Unit CE 0051

Description: Transepithelial piece with a rotational connection to connect to the dental implant and a hexalobular upper structure that connects to the attachment that will hold the dental prosthesis.

Intended use: To provide a support mechanism for the attachment that holds the prosthetic restoration in place, used for replacing dental work in order to restore masticatory function.

Labelling: The description on the label provides information about:
- Gingival height value (G shown in mm)
- Compatibility code (Comp. 0000)
- Maximum tightening torque (shown in N cm)

Variations:
• Gingival height (G): Depending on the Straight Multi-Unit model, there are a number of variations with different gingival heights. Multi-Units with different gingival heights facilitate the work when the gingival margins are at different levels.

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

2) TiBase® CE 0051

Description: Metal attachment made to connect to the Straight Multi-Unit.

Intended use: To provide a support mechanism for the prosthetic restoration, used for replacing dental work in order to restore masticatory function.

Labelling: The description on the label provides information about:
• Multi-Unit DAS system identification
• Rotational/non-rotational identification
• Gingival height value (G shown in mm)
• Value of cemented height (HC given in mm), exclusive to the 3TiBase®.

Variations:
• Rotational TiBase®: Attachment suitable for making bridges, bars and multiple structures.
• Anti-rotational TiBase®: Attachment suitable for making 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.

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

3) Screws CE 0051

Description: Threaded device manufactured to connect to the Straight Multi-Unit.

Intended use: To fix attachments and/or dental prostheses (temporary or permanent) to the Straight Multi-Unit.

Labelling: The description on the label provides information about:
• Screw head connection
• Multi-Unit DAS system identification
• Metrics (M)
• Total length (L in mm)
• Maximum tightening torque (shown in N cm)

Variations:
• Straight Screw: Screw model suitable for milled structures that do not require angulation in the screw access channel. Caution: The proper screwdriver must be used (depending on the screw head connection type) to ensure correct fastening and prevent stripping.

• Dynamic Screws: Screw model suitable for milled structures that may or may not require angulation in the screw access channel. Caution: For proper functioning, only the "Dynamic Screwdriver" should be used, enabling the screw to be fastened at an angle and to prevent stripping the head.

• Temporary Dynamic Screw: Screw model suitable for fastening milled temporary structures or printed ones made of soft materials (PEEK, PMMA, etc.). Enables angulation in the screw access channel. Caution: For proper functioning, only the "Dynamic Screwdriver" should be used, enabling the screw to be fastened at an angle and to prevent stripping the head.

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

4) Healing Cap CE 0051

Description: Threaded metal attachment to be connected directly to the Straight Multi-Unit when the healing process is not yet complete.

Intended use: To prevent the gum from healing over the Straight Multi-Unit, thus preserving the space to connect the future prosthesis once osseointegration is complete.

Labelling: The description on the label provides information about:
• Multi-Unit DAS system identification
• Connection using compatible screwdriver
• Maximum tightening torque (shown in N cm)
• Cap type 2P (in the case of the healing cap with captive screw)

Variations:
• Healing cap: formed by a single piece.
• Healing cap 2P: formed by 2 pieces.
• Regular "R": recommended for use on incisors and canine teeth.
• Wide "W": recommended for use on molars and premolars.
*The "R" and "W" configurations are available in both the healing cap and the healing cap 2P.

Engraving: The cap is engraved with the system identification "DAS-MU" and "R" or "W" model on the flat side of the device to make it easier to identify in the mouth.

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

5) Impression coping CE

Description: Tool or utensil that aids in handling and threading the system.

Intended use: To take an impression of the position of the implant in order to transfer it to a working model for the dental technician to use in the open-tray impression transfer process.

Labelling: The description on the label provides information about:
• Multi-Unit DAS system identification
• Retaining screw head connection
• Impression coping connection: (R rotating/NR non-rotating)

Variations:
• Rotating Impression coping: Device that connects with the Multi-Unit, allowing movement and rotation.
• Non- rotating impression coping: Device that connects with the Multi-Unit, without movements or rotation.

Material: Grade 5 titanium alloy (Ti 6Al 4V) compliant with international standards ASTM F136-13 and ISO 5832-3.

6) Screwdriver CE

Description: Tool or utensil that aids in handling and threading the system.

Intended use: To perform assembly and/or placement of the system, allowing the proper tightening torque to be applied.

Labelling: The description on the label provides information about:
• Head type
• Total length
• Multi-Unit DAS system identification (in the case of the Multi-Unit DAS Screwdrivers)
• Geometry of the handle (in the case of the square 4x4 Multi-Unit DAS Screwdriver)

Variations:
• Dynamic Screwdriver: Tool for handling and threading dynamic screws.
• Screwdriver: Tool for handling and threading straight screws.

• Multi-Unit DAS Screwdriver: Tool for handling and threading Multi-Units.

Material: Stainless steel, except for the Multi-Unit DAS Screwdrivers, which are made of Grade 5 titanium alloy (Ti 6Al 4V) compliant with international standards ASTM F136-13 and ISO 5832-3.

7) Ratchet CE

Description: Plastic device that connects to the Multi-Unit product.

Intended use: To firmly hold the Multi-Unit when carrying it to the patient's mouth so there is no risk of it falling, while also facilitating positioning.

Labelling: The description on the label provides information about:
• Multi-Unit DAS system identification

Material: PEEK™ CLASSIX, a biocompatible thermoplastic polymer specially designed for medical use.

8) Scanbody with screw CE

Description: Plastic device with mechanical connection, to be connected to the Straight Multi-Unit and to a screw for fastening.

Intended use: To be attached to the Straight Multi-Unit in order to detect the position and orientation of the dental implant in scanning processes.

Labelling: The description on the label provides information about:
• Multi-Unit DAS system identification
• Scanbody height (H given in mm)
• Scanbody connection (R rotating/NR non-rotating)
• Screw head connection
• Maximum tightening torque (shown in N cm)

Engraving: The Scanbody is engraved with the system identification "DAS-MU" and the symbol distinguishing it as property of Talladium España S.L.

Materials: Scanbody made of PEEKTM CLASSIX, a biocompatible thermoplastic polymer specially designed for medical use. Fixation screw made of Grade 5 titanium alloy (Ti 6Al 4V) compliant with international standards ASTM F136-13 and ISO 5832-3, with anodised surface.

9) ScAnalog CE

Description: Plastic device with a mechanical connection to connect to the impression taken.

Intended use: To be attached to the impression taken in the bite registration in order to detect the position and orientation of the dental implant in scanning processes.

Labelling: The description on the label provides information about:
• Multi-Unit DAS system identification

Laser engraving: The Scanbody is engraved with the system identification "DAS-MU" and the symbol distinguishing it as property of Talladium España S.L.

Material: PEEK™ CLASSIX, a biocompatible thermoplastic polymer specially designed for medical use.

10) Analog CE

Description: A device with a mechanical connection that replicates the Straight Multi-Unit connection.

Intended use: To simulate the Straight Multi-Unit connection in prosthetic models and for positioning and orientation.

Labelling: The description on the label provides information about:
• Multi-Unit DAS system identification

Variations:
• Analog: Suitable for prosthetic working models made of plaster.
• Digital Analog: Suitable for 3D printing dental models made through an additive manufacturing process or a 5-axis machine milling process. The analog has a concave notch to make it easier to anchor in the model. The longitudinal cut of the piece prevents rotation on the X and Y axes and screwed fastening prevents movement on the Z axis. It has a screw for fastening.
Material: The analog is made of stainless steel. The digital analog is made of Grade 5 titanium alloy (Ti 6Al 4V) compliant with international standards ASTM F136-13 and ISO 5832-3, with anodised surface. The fixation screw is made of stainless steel.

Material: The analog is made of stainless steel. The digital analog is made of Grade 5 titanium alloy (Ti 6Al 4V) compliant with international standards ASTM F136-13 and ISO 5832-3, with anodised surface. The fixation screw is made of stainless steel.

3. INDICATIONS

The Multi-Unit system is composed of a wide range of prosthetic components that directly connect to endosseous dental implants, designed for use in prosthetic restoration for fully or partially edentulous patients.

4. CONTRAINDICATIONS

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

5. WARNINGS

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

The system components facilitate clinical and laboratory work. The clinical professional is responsible for using each product according to these instructions for use and deciding whether it is appropriate for a specific patient, in order to obtain the best results.

Products labelled as single-use items cannot be reused under any circumstances, in order to avoid a loss of functionality and the risk of cross-infection among patients. Talladium España S.L. accepts no liability whatsoever for any attempted reuse.

6. PRECAUTIONS

Check the restrictions of use on the label. Pay attention to the measurements, threading phases and dimensions of the product to be used, as the proper combination of components depends on the choices made. Ensure that you do not mix up system compatibilities and pay attention to implant-attachment and screw-screwdriver connection elements.

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

It is important to use the devices exclusively with compatible products; otherwise the device may be damaged, the scanning results could be erroneous and/or the prosthesis could be made incorrectly. In the worst-case scenario, the implant could be damaged.
Use of the screws:

• Do not use the same screw in the laboratory (manufacturing process) as in the clinic (placement of the prosthesis in the patient's mouth). Do not use screws that are not in their original sealed packaging for final fixation of the prosthesis.

• Like any other metal subject to constant loads, titanium may suffer fatigue, reducing its mechanical strength. To ensure that the prosthesis functions properly on the implant, the anchoring system must be secured. Therefore, we advise you to replace any screws that show signs of wear or defects.

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

Specific precautions for TiBase® and Straight Multi-Units:

• Do not use TiBase® or Straight Multi-Units in narrow platform implants for posterior restorations (molars and premolars) because the system may fail.

Handling reusable products:

• The shelf life of reusable products depends on diverse factors that include the method, length of use and handling between each use. Therefore, thorough inspections and functional tests must be conducted prior to use. Any instruments that have rusted surfaces must be discarded. Even slightly corroded instruments may no longer be biocompatible.

• Prolonged use of plastic devices may lead them to become misshapen. If you find any lateral displacement in the positioning of the device or if it does not thread properly, it must be replaced.

• Under normal conditions and following the specifications outlined in the instructions for use, it has been verified that the Multi-Unit DAS Screwdriver can be reused for up to 30 cycles of use. However, prior to use, the pertinent inspections indicated in point one above must be conducted.

Additional precautions for clinical procedure:

• The products are NOT sterile on delivery; therefore they must be cleaned, disinfected and sterilised prior to intraoral use (see the section on Cleaning and Sterilisation).

• The products must be securely fastened so as to prevent them from getting caught in the vacuum during intraoral use or being accidentally swallowed by the patient.

• If recently implanted implants are loaded immediately, components with screws must be handled manually and with extreme care, waiting for osseointegration to take place before tightening to the specific torque.

• Special care must be taken when threading the attachments that hold the reconstructions so as not to cause unnecessary tension in the implant inserted into the bone. The seating may become obstructed after surgery or healing so it must be inspected and cleaned to ensure that nothing prevents proper functioning. Take an X-ray to ensure that the prosthesis is correctly positioned, focusing on the connection head, with a 90-degree angle in relation to its axis.

• The life cycle of healing caps and attachments used in temporary prostheses may be no longer than 6 months.

7. PROCEDURE FOR USE

The system affords several possibilities and solutions for the creation of dental prostheses, depending on the specific characteristics of each case. The products are NOT sterile on delivery; therefore they must be cleaned, disinfected and sterilised prior to intraoral use (see the section on Cleaning and Sterilisation). It is important to verify that all the components are compatible with each other before starting any process.

Placement of the Straight Multi-Unit at the clinic:

1. **After surgery, the implant connection area may become obstructed, so it must be inspected and cleaned before adding any kind of attachment.**
2. Fasten the Straight Multi-Unit to the carrier. The connection between the two must be firm, without lateral displacement.
3. Aided by the carrier, position the Straight Multi-Unit in the implant (see Figure 1). Remove the carrier with a sideways movement. Check that the Multi-Unit connection area is clean and free of debris. We recommend verifying whether the device is properly seated with the implant by taking an X-ray.
4. After verifying the positioning, apply the tightening torque on the device using the Multi-Unit Screwdriver. Take care not to exceed 30N·cm of torque.
Warning: Applying more torque than recommended could break or damage the Multi-Unit and/or the dental implant.
5. Use the healing cap if needed. This device protects the Multi-Unit connection and helps maintain, stabilise and form the soft tissues during the healing process. Position the cap on top of the Straight Multi-Unit and screw it on using a compatible screwdriver. The torque applied should be 10N·cm.
Warning: Applying more torque than recommended could break or damage the cap, the Multi-Unit and/or the dental implant.

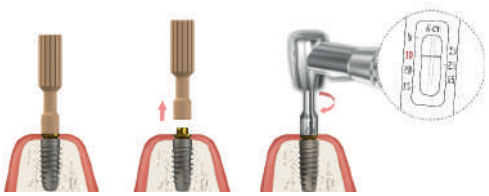

Figure 1

The system offers several possibilities for creating permanent or temporary prostheses. These are detailed below, taking into account whether an intraoral or extraoral scan is used to create the working model.

Intraoral scanning process at the clinic:

1. Remove the healing cap or temporary restoration (if applicable) and clean and dry the entire area.
2. There are the bolted Scanbodys available for scanning the patient's mouth. In this case, the technician should place the Scanbody on top of the Multi-Unit. To facilitate identification, the device has been engraved with the system code "DAS-MU" on the side. The compatible screwdriver must be used to tighten the screw.
3. If it is necessary to adjust the angulation, bear in mind that the longitudinal cut of the Scanbody corresponds with the opposite side, where the angulated channel will be located.
4. Once it is correctly positioned, fasten the Scanbody on the implant by applying the correct torque (5N·cm), using the compatible screwdriver. Warning: Applying more torque than recommended could break or damage the screw.
5. Using a dental mirror, verify that there are no spaces or gaps between the base of the Scanbody and the surface of the Multi-Unit (if there are, the position of the Scanbody should be adjusted).
6. Start scanning.

Extraoral scanning process:

At the clinic:
1. Remove the healing cap or temporary restoration (if applicable) and clean and dry the entire area.
2. Insert the impression abutment into the Straight Multi-Unit and ensure the interfacial geometry matches. Check that it is correctly seated.
3. Tighten, either manually or by using a screwdriver, the abutment screw (5-10N cm). Warning: Applying more torque than recommended could break or damage the device and/or the implant.
4. Test the custom-made perforated impression tray in the patient's mouth to ensure that the perforations line up.
5. Cover the impression post with a suitable impression material.
6. Fill the impression tray with the impression material and place it into the patient's mouth.
7. Wait for the material to set.
8. Continue by unscrewing the abutment screw.
9. Once unscrewed, remove the impression. The impression post should stay in the impression material. Thread the retaining screw back into the impression taken before sending it to the laboratory.
10. Check that the implant is clean and impurity-free.
11. Place the healing cap back over the Multi-Unit.

At laboratory:
1. Remove the retaining screw so that the analog can be placed into the impression taken. Tighten the screw again.
2. Pour the material into the impression model.
3. Wait for it to set.
4. Loosen the abutment screw from the impression abutment.
5. Separate the impression from the model.
6. Place the Scanbody with screw on top of the analog.
7. If it is necessary to adjust the angulation, bear in mind that the longitudinal cut of the Scanbody corresponds with the opposite side, where the angulated channel will be located.
8. Once it is correctly positioned, fasten the Scanbody on the analog by applying the correct torque (5N·cm), using the compatible screwdriver. Warning: Applying more torque than recommended could break or damage the screw.
9. Verify that there are no spaces or gaps between the base of the Scanbody and the surface of the analog (if there are, the position of the Scanbody should be adjusted).
10. Start scanning

• If using ScAnalog

1. Position the ScAnalog on the impression taken in the bite registration. Bear in mind that the longitudinal outer cut corresponds with the opposite side of the screw channel in the future prosthesis.
2. Verify that there are no spaces or lateral movements in the connection between the ScAnalog and the impression taken.
3. Fasten it with the screw in the impression taken. You should tighten the screw manually with the appropriate screwdriver, because the aim is just to hold the ScAnalog in position.
4. When it is in the right position, start scanning.

Model impression and prosthesis design:

1. To digitally design the prosthesis, CAD libraries should be used for the Multi-Unit DAS in accordance with the compatibility of the Straight Multi-Unit used. To do this, be sure to choose the number indicated for compatibility (the code can be found in the description on the product label). You can also check the Multi-Unit Library Codes document sent with the CAD library (available at www.dynamicabutment.com). A poor choice of compatibility will lead to incorrect performance of the work, given the variations in the parameters of each one. Talladium España S.L. accepts no liability whatsoever for a poor choice in the compatibility of the library.
2. There are several libraries available, adapted to the products used. Take care to use the appropriate library, depending on the work you are performing.
3. It is important to choose the proper gingival height, depending on the Multi-Unit used. Therefore, communication between the clinical technician and the laboratory technician must be precise and thorough.
4. A poor choice of compatibility and/or gingival height will lead to incorrect performance of the work, given the variations in the parameters in each case. Talladium España S.L. accepts no liability whatsoever for a poor choice in the compatibility and/or gingival height of the library.
5. The library allows you the option of working with the TiBase®, the structure of which makes it possible to adjust the angle of the screw access channel or with the 3TiBase® for cases.
requiring a larger support surface to achieve a stronger, more resistant structure.

Note: Check the guidelines for use of the DAS for Multi-Unit CAD libraries at www.dynamicabutment.com. Remember that Talladium España S.L. has a customer service hotline (Tel. +34 973 289 580) to answer questions and help install the CAD software. For further information about the complementary products, you may check the relevant instructions for use at www.das-eifu.com.

Prosthesis placement:

a) Remove the healing cap or temporary restoration (if applicable) and clean and dry the entire area.
b) Always read the manufacturer's instructions for use of the original implants.
c) Place the prosthesis on the Multi-Unit and tighten the screws with the recommended torque (25N·cm).
d) Only the compatible screwdriver should be used to tighten the screws. Warning: Applying more torque than recommended could break or damage the screw, the Multi-Unit or even the implant, in the worst case.
e) Remember that there is a temporary Dynamic Screw, which is specially indicated in the case of temporary prostheses made of soft materials (PEEK, PMMA).
f) Close the screw access channel

8. CLEANING AND STERILISATION

The products are NOT sterile on delivery; therefore they must be cleaned, disinfected and sterilised directly before being used in the mouth.

Remove the product from its packaging and clean and disinfect it, preferably in an ultrasonic bath with the usual cleaning solution and disinfectant for medical instruments.

Always handle the product with powder-free gloves.

The recommended sterilisation method is humid heat in an autoclave, applying the standard cycle of 121°C for 15 minutes, in accordance with UNE ISO 17665-1.
The technician must sterilise all the surgical instruments before use and prevent the product from coming into contact with non-sterile objects, to reduce the risk of contamination as much as possible.

9. TRACEABILITY

At the bottom of the label attached to the product there are 3 tabs containing information about traceability of the device. These additional labels can be detached and added to the patient's card and (clinic and laboratory) records. It is important to record this information to avoid future mishaps and to ensure that the proper choices are made in future replacements, as well as inform all the professionals about the required compatible instruments.

10. MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION

The safety and compatibility of this system in magnetic resonance imaging MRI) settings has not been assessed. No tests for heating, displacement or image interference have been conducted in MRI settings.

11. STORAGE

The product must be kept in its original packaging at room temperature, between 18 and 25°C, for example, in a dry place out of direct sunlight.

12. DISPOSAL

All Talladium España S.L. products must be handled at the end of their service life as stipulated in the laws and regulations of the competent authorities

Warning: Please report any serious incidents related to the product to the manufacturer, Talladium España S.L., and to the competent authorities.

SYMBOLS LEGEND

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