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DYNAMIC ABUTMENT® SOLUTIONS

Intraoral System
Instructions for use

Company details:
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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

TYPE OF PRODUCTS

1) Intraoral adapter CE

Description: Piece with connection to the dental implant and to the compatible intraoral scanbody.

Intended purpose: To serve as a connection element between the dental implant and the intraoral scanbody.

Labelling: The description on the label provides information on:
• Type of compatible scanbody
• Compatibility code (Comp. 0000)
• Maximum tightening torque (given in N.cm)
• Value of gingival height (G given in mm) in the intraoral adapters with G≠1.
• "Tiny" identification in the case of the adapters designed specifically for implants with small platform diameter.

Variants:
• Screw with magnet and intermediate body: adapter appropriate for implants with internal connection. The intermediate body has, in the lower part, the connection with the compatible dental implant and, in the upper part, the connection with the corresponding scanbody.
• Screw with magnet: adapter appropriate for implants with external connection.
• Gingival height (G): The adapters with intermediate body are available in different gingival heights. A greater gingival height facilitate work where the gingival margins are uneven.

Materials: Screw and intermediate body made of Grade 5 titanium alloy (Ti 6Al 4V) compliant with international standards ASTM F136-13 and ISO 5832-3. The pieces are anodized depending on the compatibility. Magnet made of neodymium with gold coating.

2) Intraoral Scanbody CE

Description: A part with a magnet inside that is fixed and fits exactly to the intraoral adapter.

Intended purpose: It detects the position and orientation of the dental implant in the scanning processes. Since it is not screwed to the implant, there are no holes in the upper section (Z-axis) which improves the scan reading and accuracy.

Labelling: The description on the label provides information on:
• Type of scanbody
• Total height (H expressed in mm). To recognize the height in the scanned file, the scanbody has marks along its longitudinal section: 1 point corresponds to the 8mm or 9mm height scanbody, 2 points corresponds to the 10mm, 3 marks is 12mm and 4 marks means 15mm.

Engraving: The intraoral scanbody has engraved the type of scanbody and the total height (Ex. HA-10), the batch number and the Talladium España S.L. identification symbol.

Materials: Scanbody made of PEEK™ CLASSIX, biocompatible thermoplastic polymer, specially designed for healthcare use. Magnet made of neodymium with gold coating.

3) Digital analog CE

Description: A device with a mechanized connection that replicates the dental implant connection. It is 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.

Intended purpose: To simulate the dental implant connection in prosthetic models and for positioning and orientation.

Labelling: The description on the label provides information on:

• Compatibiliy code (Comp.0000)

Material: Stainless steel

4) Screwdriver for intraoral adapter CE

Description: Tool or implement that helps manipulate intraoral adapter.

Intended purpose: Allows the proper attachment of the intraoral adapter, making it easier to position and threading directly onto the implant.

Labelling: The description on the label provides information on:
• Total lenght (L expressed in mm)
• "Tiny" identification in the case of the intraoral screwdriver compatible with the Tiny intraoral adapter.

Variants: Intraoral screwdrivers are available in 3 different lengths depending on user needs.

Materials: Stainless Steel.

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 Micro-Scan system from Talladium España, SL is based on state-of-the-art technology that ensures the highest precision and accuracy during the scanning and milling process in the clinic and laboratory. Its use allows the professional to work with high precision in intraoral and extraoral scan CAD processes, incorporating the dynamic working system.

5. CONTRAINDICATIONS

Titanium products are contraindicated for patients who are allergic or hypersensitive to the titanium alloy Ti6Al4V.
Products containing magnets are contraindicated in people who use pacemakers or any electronic or metallic device inside the body.
Products containing magnets are contraindicated in people who are allergic to nickel or neodymium.

6. WARNINGS

The system components facilitate clinical and laboratory work. The clinical professional is responsible for using each product according to these instructions for use 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.

7. PRECAUTIONS

Check the restrictions of use on the label. The different compatibilities of the adapters and scanbodies that make up the system catalogue should not be confused, and attention must be paid to the connecting components.

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, under normal conditions and when following the specifications detailed in the instructions for use, the intraoral adapter can be reuse a maximum of 15 cycles of use. In the case of the intraoral scanbody, the precision parameters and its functionality are maintained for 3 cycles of use. However, close inspection and operational tests are needed prior to reusing it. If instruments are found to be worn or have oxidized surfaces, dispose of them. Even the slightest corrosion means the instruments are no longer biocompatible.

All intraoral system and Micro-Scan system products, except the digital analog, are intended to be continuously used inside the mouth for a short time (less than 60 minutes).

Specific precautions for intraoral scanbody:

Do not reuse the intraoral scanbody if it has received excessive blows or pressure after handling (including accidental bites by the patient), as the total height may be affected.

Continued use of the scanbody may lead to internal wear on the geometry. If professionals detectthese problems, the scanbody must be replaced with a new one.

The intraoral scanbody should be used in the temperature range 20-24°C to ensure measurement accuracy.

Specific precautions for intraoral adapter

The intraoral adapter should only be handled with the Talladium España, SL intraoral adapter screwdriver.

A tiny intraoral adapter is available for the smaller diameter platform implants. This adapter must be exclusively handled with the Tiny intraoral adapter screwdriver from Talladium España S.L

All adapters have a maximum tightening torque of 5 N•cm. It must be manually screwed.

Specific precaution for parts containing magnets:

Do not touch any magnetic type information medium (e.g. credit cards or computers).

Do not let the magnet exceed the maximum working temperature (150°C) by heating.

Do not bring together two magnets of different materials; one of the features of the two could be modified.

Specific precaution when using Micro-Scan system components within the oral cavity:

To prevent the accidental swallowing of any of the devices in the system, take the following precautions:

(1) The intraoral Scanbody has a notch at mid-height; tie the scanbody with dental floss and check the clamping to prevent accidental swallowing.

(2) The handling, positioning, threading and unscrewing of the intraoral adapter in the implant should be performed with the intraoral screwdriver, which guarantees additional grip for the device, preventing it from becoming detached within the oral cavity.

8. OPERATIONAL USAGE

In the clinic

1) Before inserting any attachments, ensure all components are clean and undamaged. Check that all the components are compatible.

2) The implant connection area may be blocked after surgery or healing, so it should be checked and cleaned before inserting the adapter. Once the canal has been cleaned, position the adapter correctly.

3) It is important for adapters with intermediate body to ensure that the geometry of the part connects perfectly with the implant connection before applying the prescribed tightening torque. If not, positioning the scanbody later may not be exact and may result in an erroneous measurement and damage to the implant, in the worst of cases.

4) Make sure that the adapter is correctly positioned using the scanning mirror. See Fig.1. In the picture you can see a grey coloured area on the intraoral adapter. It is important that you check that this area fits well and does not protrude from the implant surface.

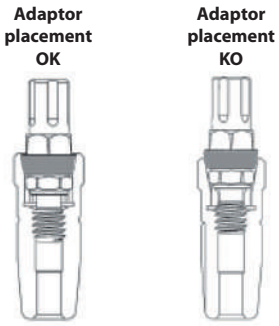
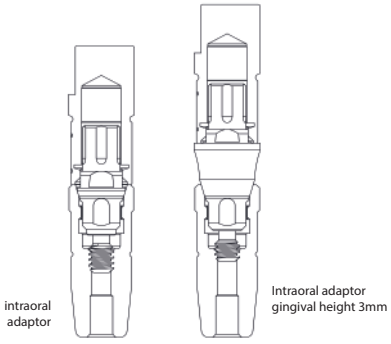


Fig. 1

5) Once the position of the adapter has been verified, apply the prescribed torque (5N·cm). Caution must be taken when applying torque manually, as excessive torque may cause unnecessary stress on the implant inserted into the bone.

NOTE: Adapters with a gingival height of 3mm will always protrude from the surface of the implant. The geometry of this type of adapter must be carefully positioned to then tighten the screw.



6) When the adapter is properly threaded, insert the scanbody. Position the part on the adapter until the shapes of both are matching and are magnetized to each other.

*A standard intraoral adapter is used: Using the scanning mirror, make sure that there are no gaps between the base of the scanbody and the surface of the implant. (If so, the position of the adapter or the scanbody must be checked).

* An intraoral adapter with a gingival height of 3 mm is used: With this type of adapter, the scanbody does not close on the surface of the implant, instead the closure occurs between the base of the scanbody and the surface of the adapter platform. Use the dental mirror to ensure there are no spaces/gaps.

7) Verify that the adapter and the scanbody are properly positioned, before starting the scan, by X-ray (focusing it toward the implant connection and at a 90-degree angle to its axis). See Fig2. And Fig 3. Four situations can be found in the radiography:

Standard intraoral adapter (Fig. 2):

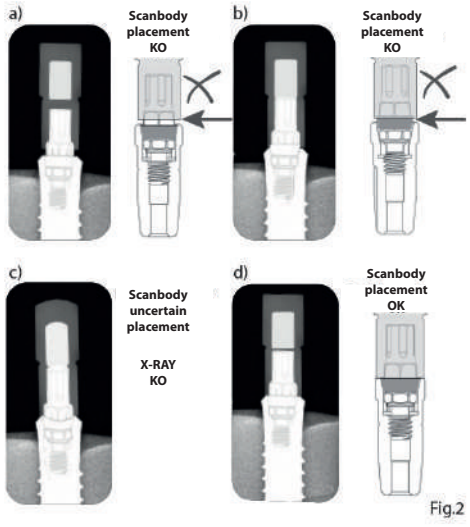


Fig.2

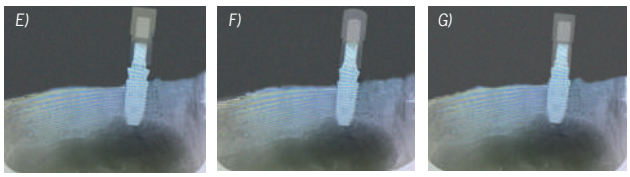
a) If the adapter is well positioned but the scanbody is not, you will notice that the distance between the magnets is remarkable. Check that there is no obstacle between the scanbody and the implant surface. Slightly rotate the scanbody so that its geometry matches that of the adapter and they are joined by magnetization.

b) If you observe that there is no separation between the magnets of both components, you must consider that the adapter connection is not correctly connected to the implant and/or the screw is not sufficiently threaded, therefore, you must repeat its positioning.

c) If you notice that the upper area of the magnet has a convex, non-flat surface, the X-ray is not in proper focus. In this case the positioning cannot be assessed, and the X-ray must be repeated.

d) If both components are correctly positioned you should observe a slight distance between the magnets of both devices.

Intraoral adapter with a gingival height of 3mm (Fig. 3)



e) If the adapter is correctly positioned while the scanbody is not, there will be a clear distance between the magnets. Check that there is nothing between the scanbody and the adapter platform surface. Rotate the scanbody gently until its geometry matches that of the adapter and join them together using magnetisation.

f) If the upper section of the magnet is convex instead of flat, the x-ray will not focus correctly. Here, the positioning cannot be ascertained, and the x-ray must be redone.

g) If both components are in the correct position, there should be a slight gap between the magnets on the two devices.

8) If a correction of the angulation is necessary, whether using a standard intraoral adapter or an adapter with a gingival height, bear in mind that the longitudinal cut of the scanbody corresponds to the side opposite to where the angled channel will be located. In these cases, the scanbody will have as many possible positions as faces on the connection geometry for the compatibility in which you are working.

9) If the positioning is correct, perform the scan using the usual procedure and the manufacturer's instructions. Take the necessary precautions in the scan so that no body or medium interferes with the scanbody, as any contact could alter the measurement.

NOTE: In case of using the **intraoral scanbody type HH** compatible with **Bego 3.0** (compatibility code 0049) stands 0,15mm above the implant perimeter. These technical specifications must be taken into account when doing surgery.

A 3D model with a digital analog should be made as a validation platform in the laboratory. It is advisable to work with a removable gingival mask to ensure the passive fit of the future prosthesis.

In the laboratory

The Micro-Scan system can also be used with the traditional extraoral scanning procedure. Its use makes several choices possible regarding the realization of the final prosthesis, either through TiBase, pre-milling or direct to implant.

9. CLEANING AND STERILIZATION

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 product until all visible dirt and residue are removed and then put it into the ultrasonic cleaner with a cleaning solution and disinfectant. Rinse with purified or sterile water.

If necessary, repeat the cleaning steps. Dry the parts using filtrated compressed medical air (if available) or single-use wipes that are clean and free of residues

The products containing magnets must be cleaned independently to ensure that no metal residue is adhered to the inside or outside of the part. To maintain the correct functionality of the magnet-containing parts, cleaning must be done manually and should not be inserted in an ultrasonic bath.

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 intraoral scanbody, a period of at least 4 hours after sterilisation must be left before use in the mouth to guarantee the correct functioning of the system. In this way, the proper functioning of the system and the piece's precision is guaranteed.

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 (20-24ºC) 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.

SYMBOL LEGEND

CE	CE Marking		Manufacturer
	Consult instructions for use		Date of manufacturer
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		