

SCOPE:

This instructions has the follow scope;

- Performance; Support piece for dental prosthesis.

o Titanium. material

• Products: Straight abutments, Angled abutments, Tapered abutments, Titanium tapered abutment, Titanium Ucla abutments, Ball abutments.

o Gold.material

• Product: Gold base ucla.

- Performance, piece with thread that will be used as joining element between the abutment and the implant or covering over the implant.

o Material titanium.

• Products; Cover screws, Retaining screws, Healing abutments, Caps for tapered abutments

This classification has been made based on performance and different materials.

These products are compatible with Inhex and Osseous Dental Implants.

DESCRIPTION:

Prosthetic system is made of Grade V Titanium and gold alloy a biocompatible material. The prostheses are manufactured with High-precision machinery with a margin of error of ± 0.005 mm and a tolerance of ± 0.01 mm

INDICATIONS

Prosthetic system is intended to be used as anchor for fixed or semi-fixed dental crowns, bridges and overdentures in patients with partial or full edentulism both in the upper and lower jaw

CONTRAINDICATIONS

Contraindications include:

1.- Cases which the remaining jaw bone is too diminished to allow implant placement

2.- Patients allergic to titanium alloy and gold base materials.

3.- Patients with insufficient mental health precluding patient cooperation

4.- Patients with abuse of drugs and alcohol

5.- Patients who have suffered myocardial infarct last year, oral infections, or malignancies

6.- Patients with uncontrolled diabetes or blood disorders

WARNINGS

To be used by qualified professionals only (dentists, doctors experts in dentistry or stomatology, maxillofacial surgeons).

For the safety and effectiveness of use of Inhex / Osseous Prosthetic System, it is strongly suggested that specific training be carried out, as well as the study of appropriate textbooks. THESE INSTRUCTIONS ARE NOT INTENDED TO BE SUBSTITUTE FOR ADEQUATE TRAINING. Responsibility for the proper choice of the patient, the adequate training, the experience in implant placement of the implants, and provision of appropriate information for informed consent devolves upon the practitioner. Improper technique may result in implant failure and/or loss of supportive bone. Mozo Grau is not able to control the application and processing of our products, which are user's responsibility.

Therefore, Mozo Grau will not accept liability for damage arising thereof.

Information to allergen

The materials used to manufacture the abutments are:

Abutments; Titanium Gr. 5 (Ti, Al, V, Fe, O, N, C)

Gold Base Ucla; Au, Pt, Pd, Ir.

PRECAUTIONS

The Inhex / Osseous Prosthetic System is a single-use product. Re-use of these items entails an increase in product failure risk as functionality cannot be guaranteed if re-used. Titanium is a metal which may be easily scratched during use. A scratched surface is more difficult to clean existing, therefore, a greater risk of contamination.

CLEANING AND STERILIZATION

It is recommendable to clean, and sterilize all the Inhex / Osseous Prosthetic before use after delivery since products are supplied non-sterile (they must be cleaned and disinfected after having removed packaging).

A proper cleaning and disinfection are essential prerequisites for proper sterilization.

Recommended cleaning method

• Immerse devices in cleaning solution.

-Mozo Grau does not recommended any specific cleaning and/or disinfection agents. Only specifically formulated cleaning agents should be used. Solution with a pH value of 7-10 and a temperature of approx. 35°C/95°C.

• Rinse and flush with purified or sterile water. Mineral residues from hard water can result in staining of the device.

• Dry with compressed air or wipes.

Please do not forget that the disinfectant used in the pre-treatment is only for personal protection and does not replace the later disinfection after cleaning.

Method of sterilization

• Place product inside sterilization bags.

• Place the product inside the autoclave. Do not sterilize different types of materials in contact.

• Sterilization in autoclave by moist heat 134 ° C (273 ° F) - 5 minutes. Make sure elements inside the autoclave are not rusty

• The exposure temperature for products and sterilization trays shall not exceed 137 ° C.

• When the autoclave is finished, remove the product form the autoclave.

SURGICAL AND PROSTHETIC PROCEDURES

For detailed information of the surgical and prosthetic procedures refer to the Surgical and Prosthetic manuals.

The following considerations should be reviewed prior to the restorative phase:

- Quantity, quality and health of soft and hard tissues

- Implant stability

- Implant position and abutment selection

- Occlusal analysis

- Oral hygiene assessment

A mechanical fracture of implants or bridges may occur. A blow to the jaw or mouth, or the stress concentration coming from the bridge, may result in such mechanical failures. Do not use small diameter implants in high load applications. Mobility, bone loss, and / or pain and infection may indicate that the implant is failing. On rare occasions when the implant osseointegration fails, the implant has to be removed, then, the bone heals and the condition of the jaw and mouth is virtually the same as if the procedure had not been performed. The loss of implant stability (osseointegration failure) and loss of the bridge are possible incidents after surgery. Lack of quality and quantity of remaining bone, infection and systemic diseases (diabetes, etc) are some potential causes of stability loss

Recommended torque level is 30Ncm for abutment attaches directly to implant and 20Ncm for the rest of abutments.

In the case of using our Gold Base Ucla, the recommendation is; Cast using Gold Alloys 60/19.

PACKAGING AND STORAGE

Prosthetic system is supplied clean but not sterile. All information about the product is labeled. Product packaging is performed individually.

This product does not need special storage and transport conditions because raw material is stable under pressure and atmospheric temperature conditions. it is recommended to store the product at temperatures under 50°C and humidity limit up to 70%

LABELLING SYMBOLS

Manufacturing



Consult instructions for use



Reference



CE Mark



Do not reuse



Batch code

MANUFACTURE**MANUFACTURE**

MOZOGRAU®, S.A.

C/ Santiago López González, 7
47197 VALLADOLID (SPAIN)

Tel. +34 983211 312 fax: +34 983 304 021

e-mail: sales@ticareimplants.com

www.ticareimplants.com