

External Hexagon Implant,
E y G Medical System

Instructions for use
System of Dental implant
E y G Medical System.

Read the instructions



Connection External Hexagon



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GESTION
DE LA CALIDAD

RI 13485-29

Sistema de Gestión de la Calidad
Certificado por IRAM
Norma IRAM-ISO 13.485:2019



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Do not reuse

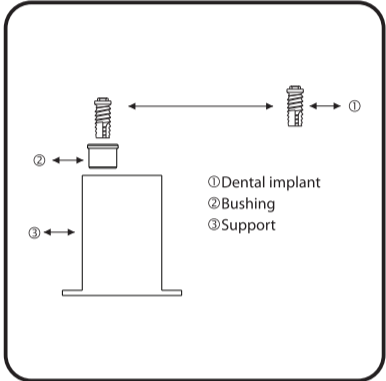


Read the instructions before use



Sterilized by Gamma-Ray

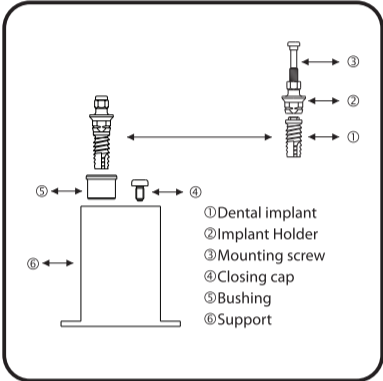
Reference without assembler without closing cap (SMT)



Connection External Hexagon



Reference with assembler and closing cap (SUR)



Connection External Hexagon



General information.

Description:

The **HE E y G Medical System Implant**, is manufactured with Grade 4 Titanium (ASTM F67), and Grade 5 Titanium (ASTM F136). Subsequent to machining, the surface is sandblasted with aluminum oxide and then treated with acid, generating a roughness that facilitates bone-integration, improves its quality and reduces the times for its habilitation. In all hybrid implants, starting from the base of the hexagon are left 3mm. without sandblasting. For cases where could be bone retraction; there are also options with the entire surface blasting. The design corresponds to widely approved geometries, with external hexagon, with the conical body in the apical portion with a flight of spiral that facilitates the introduction and the initial anchorage.

Actions:

The **HE E y G Medical System Implants**, can be used in the mandible or the maxillar. They are offered in different diameters and heights to place in the cavities created in the healed or post-extraction bone.

Indications:

The **HE E y G Medical System Implant**, is designed to be used in edentulous sites in the mandible or the maxilla as a support for complete dentures, terminal or intermediate abutments for fixed bridges or partial dentures or for replacement of a single tooth.

Contraindications:

The **HE E y G Medical System Implants**, should not be used in patients with contraindicated diseases such as: blood dyscrasias, uncontrolled diabetes, hyperthyroidism, bruxism, oral infections or malignancies. The **HE E y G Medical System Implants**, should also not be used in patients with contraindicated conditions such as last year's myocardial infarction or insufficient bone support to allow the use of an appropriately sized implant. They can be used in implant-retained dentures. Not designed to withstand side loads. Implants should not be placed if the amount of bone (thickness and height) is not sufficient to cover them around.

Precautions:

The professional should use all the diagnostic methods available to him and which he considers necessary to determine if there is sufficient bone present in the proposed implant site and to locate established anatomical characteristics such as mandibular ducts, mental foramina, maxillary sinuses and adjacent teeth. Direct palpation and visual inspection of the site chosen for the implant is also necessary to determine the anatomy of the available bone. A complete clinical evaluation and adequate motivation of the patient for the procedure to be successful is essential.

Warning:

Implantation surgery is a complex and highly specialized procedure and requires special training in established Oral Implantology techniques. Dentists are strongly advised to conduct specialization courses and seminars before undertaking their first surgery. The use of an inadequate technique can lead to implant failure and substantial loss of adjacent bone.

The **HE E y G Medical System Implant**, should not be used in places or cases other than those specifically indicated. Failure to do so may result in failure of the implant and destruction of bone support.

Presentation:

The **HE E y G Medical System Implants**, are supplied in a sterile container. If the package is damaged or if the implant is contaminated for any reason, it should be discarded. The **HE E y G Medical System Implants**, are for single use only. The implants are supplied sterilized with gamma rays.

Sterile Handling Procedures:

1. The auxiliary removes the container from the bottle or pouch or carton and opens it carefully, allowing the inner container to fall freely on a sterile tray. Do not contaminate individual container.
2. The dentist opens the inner container, places a sterile implant port or a transport key, removes the implant and inserts it into the osteotomy prepared for this purpose.
3. If it is done properly, it is not necessary for anyone to touch the implant directly.

Attention:

Exclusive health care facilities and professionals use.

HE E y G Medical System Implant.

Warranty and Limitations:

The success of all dental implants depends to a large extent on the surgical technique, which must be performed with great precision. The careful selection of the patients and the final restorative prosthesis is fundamental, which must be adapted to the needs of each patient and the rest of the anatomy. The selection of an individual implant or several implants of the appropriate size and configuration for the existing anatomy is also critical to the success of the procedure.

Because E y G Medical System S.R.L. should not and cannot control factors related to the services provided by the professional, including patient selection, surgical technique and restorative techniques, their responsibility is limited to the replacement of the product by faults or other reactions or unfavorable results for the purchaser, dental professional or patient that may arise from the use of a HE E y G Medical System Implant. Titanium HE E y G Medical System Implant and pillar, are exceptionally resistant to bending and fracture. However, it is not possible to guarantee that they will not bend or fracture in the event of traumatic injuries or excessive occlusive loads.

For the above reasons, except as expressly stated herein, E y G Medical System S.R.L. makes no warranty beyond the content of this warranty or the description included on any invoice. This warranty replaces and excludes all other warranties, express or implied, including warranties of merchantability and fitness for a particular purpose. E y G Medical System S.R.L. sells its products and guarantees to buyers that they are authorized dentists and that they buy implants and pillars for their use and resale as part of the services they offer to their patients. E y G Medical System S.R.L. makes no warranty in writing to any consumer, patient or end-user and does not authorize any person to grant it on its behalf. The resources that any purchaser of an implant and pillar **HE E y G Medical System** and their obligations are limited solely and exclusively to the replacement or repair of an implant and pillar **HE E y G Medical System** defective as long as the E y G Medical System S.R.L. authorities are proven within six (6) months of delivery that was defective at the time of shipment and provided that it is returned to E y G Medical System S.R.L. for inspection and/or replacement.

E y G Medical System S.R.L. is not liable to any person for any incidental, consequential or other damages, whether the claim is of a contractual, non contractual or negligent nature.

Made by:

E y G Medical System S.R.L.
Production Plant: Av. Coronel Cardenas 2768/74
C1440EJR CABA - Argentine
Te. 54.11.2067.8472
Authorized by A.N.M.A.T. PM-2196-4

E y G Medical System S.R.L. has its Quality Management System certified according to IRAM-ISO 13485:2019 with certificate of registration No. 13485-29

Technical director:

Pharmacist Maria Carolina Ramos M.N. No. 16360

Distributed by:

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