

INSTRUCTION FOR USE

TECHNICAL NAME: DENTAL IMPLANTS (OSSEOINTEGRABLE)

TRADE NAME: DENTAL IMPLANTS

Cylindrical Biodent HEX NP 3.3 x 8.5mm
Cylindrical Biodent HEX NP 3.3 x 10mm
Cylindrical Biodent HEX NP 3.3 x 11.5mm
Cylindrical Biodent HEX NP 3.3 x 13mm
Cylindrical Biodent HEX NP 3.3 x 15mm
Cylindrical Biodent HEX RP 3.75 x 8.5mm
Cylindrical Biodent HEX RP 3.75 x 10mm
Cylindrical Biodent HEX RP 3.75 x 11.5mm
Cylindrical Biodent HEX RP 3.75 x 13mm
Cylindrical Biodent HEX RP 3.75 x 15mm
Cylindrical Biodent HEX RP 4.0 x 8.5mm
Cylindrical Biodent HEX RP 4.0 x 10mm
Cylindrical Biodent HEX RP 4.0 x 11.5mm
Cylindrical Biodent HEX RP 4.0 x 13mm
Cylindrical Biodent HEX RP 4.0 x 15mm
Cylindrical Biodent HEX RP 4.0 x 17mm
Cylindrical Biodent HEX UP 5.0 x 8.5mm
Cylindrical Biodent HEX UP 5.0 x 10mm
Cylindrical Biodent HEX UP 5.0 x 11.5mm
Cylindrical Biodent HEX UP 5.0 x 13mm
Cylindrical Biodent HEX UP 5.0 x 15mm
Conical Bioneck TRI NP 3.5 x 8mm
Conical Bioneck TRI NP 3.5 x 10mm
Conical Bioneck TRI NP 3.5 x 11.5mm
Conical Bioneck TRI NP 3.5 x 13mm
Conical Bioneck TRI NP 3.5 x 16mm
Conical Bioneck TRI NP 4.3 x 8mm
Conical Bioneck TRI NP 4.3 x 10mm
Conical Bioneck TRI NP 4.3 x 11.5mm
Conical Bioneck TRI NP 4.3 x 13mm
Conical Bioneck TRI NP 4.3 x 16mm
Conical Bioneck TRI PR 4.3 x 8mm

Conical Bioneck TRI RP 4.3 x 10mm
Conical Bioneck TRI RP 4.3 x 11.5mm
Conical Bioneck TRI RP 4.3 x 13mm
Conical Bioneck TRI RP 4.3 x 16mm
Conical Bioneck TRI UP 5.0 x 8mm
Conical Bioneck TRI UP 5.0 x 10mm
Conical Bioneck TRI UP 5.0 x 11.5mm
Conical Bioneck TRI UP 5.0 x 13mm
Conical Bioneck TRI UP 5.0 x 16mm
Conical Bioneck TRI WP 5.0 x 8mm
Conical Bioneck TRI WP 5.0 x 10mm
Conical Bioneck TRI WP 5.0 x 13mm
Conical Bioneck TRI WP 5.0 x 16mm
Cylindrical Dynamic CMI NP 3.5 x 8.5mm
Cylindrical Dynamic CMI NP 3.5 x 10mm
Cylindrical Dynamic CMI NP 3.5 x 11.5mm
Cylindrical Dynamic CMI NP 3.5 x 13mm
Cylindrical Dynamic CMI NP 3.5 x 15mm
Cylindrical Dynamic CMI RP 4.3 x 8.5mm
Cylindrical Dynamic CMI RP 4.3 x 10mm
Cylindrical Dynamic CMI RP 4.3 x 11.5mm
Cylindrical Dynamic CMI RP 4.3 x 13mm
Cylindrical Dynamic CMI RP 4.3 x 15mm
Cylindrical Dynamic CMI RP 5.0 x 8.5mm
Cylindrical Dynamic CMI RP 5.0 x 10mm
Cylindrical Dynamic CMI RP 5.0 x 11.5mm
Cylindrical Dynamic CMI RP 5.0 x 13mm
Cylindrical Dynamic CMI RP 5.0 x 15mm
Singular Conical CMI NP 3.5 x 8mm
Singular Conical CMI NP 3.5 x 10mm
Singular Conical CMI NP 3.5 x 11.5mm
Singular Conical CMI NP 3.5 x 13mm
Conical Single CMI NP 3.5 x 16mm
Single Conical CMI RP 4.3 x 8mm
Single Conical CMI RP 4.3 x 10mm
Single Conical CMI RP 4.3 x 11.5mm
Single Conical CMI RP 4.3 x 13mm
Single Conical CMI RP 4.3 x 16mm
Single Conical CMI RP 5.0 x 8mm

<i>Single Conical CMI RP 5.0 x 10mm</i>
<i>Single Conical CMI RP 5.0 x 11.5mm</i>
<i>Single Conical CMI RP 5.0 x 13mm</i>
<i>Single Conical CMI RP 5.0 x 16mm</i>
<i>Cylindrical Exakort HI 3.3 x 8mm</i>
<i>Cylindrical Exakort HI 3.3 x 10mm</i>
<i>Cylindrical Exakort HI 3.3 x 11.5mm</i>
<i>Cylindrical Exakort HI 3.3 x 13mm</i>
<i>Exakort HI 3.3 x 15mm Cylindrical</i>
<i>Cylindrical Exakort HI 3.8 x 8mm</i>
<i>Cylindrical Exakort HI 3.8 x 10mm</i>
<i>Cylindrical Exakort HI 3.8 x 11.5mm</i>
<i>Cylindrical Exakort HI 3.8 x 13mm</i>
<i>Cylindrical Exakort HI 3.8 x 15mm</i>
<i>Exakort HI 4.2 x 8mm Cylindrical</i>
<i>Exakort HI 4.2 x 10mm Cylindrical</i>
<i>Exakort HI 4.2 x 11.5mm Cylindrical</i>
<i>Exakort HI 4.2 x 13mm Cylindrical</i>
<i>Exakort HI 4.2 x 15mm Cylindrical</i>

PRODUCT DESCRIPTION:

DÉRIG Dental Implants consist of: a cylindrical or conical body, with a rough surface. This chemical treatment process increases its contact surface, thus increasing primary stability and accelerating osseointegration. The implant may have milled at the apex, distributed evenly in order to facilitate its insertion. In the longitudinal axis of the upper part of the implant there is a central thread that allows the fixation of the prosthetic component with a screw. It is produced by turning grade 4 pure titanium bars to ASTM F67.

DÉRIG Implants are supplied with Cover Screw, to protect the internal parts during osseointegration, in case the surgeon chooses to make the provisional prosthesis after this process. We have 8 groups of implants that differ from each other in terms of:

- a) **External profile:** cylindrical or conical.
- b) **Thread pitch:** 0,5 a 1,2mm.
- c) **Thread profile:** V-thread, Trapezoidal Thread and Square Thread.
- d) **External profile dimension:** Ø 3.0 to 5.0mm and lengths from 5.5 to 22mm.
- e) **Internal thread:** M1,6, M1,8, M2,0 e M2,5mm.
- f) **Prosthetic Connective Platform:** Outer hexagon, inner triangle and inner conical.
- g) **Codes:** The NP, RP, WP and UP codes refer to the implant platform size

Connection:

HEX - External Hexagon
 TRI - Internal Triple Channel
 CMI - Indexed Morse Cone
 HI - Internal Hexagon

Plataforma:

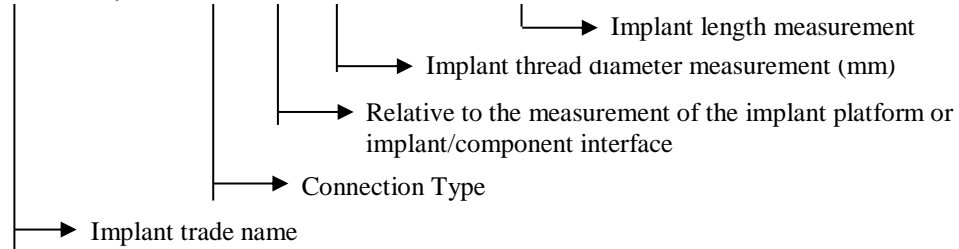
NP – Narrow Platform (Narrow platform) → receives NP componentes
 RP – Regular Platform (Regular Platform) → receives RP-UP components
 UP – Unified Platform (Unified Platform) → receives RP-UP components
 WP – Wide Platform (Large Platform) → receives WP components

Platform Code	Platform diameter measurements according to the system (mm)				
	Biodent HEX	Bioneck TRI	Dynamic CMI	Singular CMI	Exakort HI
NP	Ø3,5	Ø3,5	Ø2,75	Ø2,75	Ø3,40
RP	Ø4,1	Ø4,3	Ø2,75	Ø2,75	-
UP	Ø4,1	Ø4,3	-	-	-
WP	Ø5,1	Ø5,0	-	-	-

Example:

Conical Bioneck Implant TRI NP 4.3 x 10mm

Biodent Cylindrical Implant HEX RP 3.75 x 13mm



The DÉRIG implants are divided into 8 groups below, each group being indicated for one or more regions of the dental arch depending on the technique or surgical situation appropriate to the surgical planning of each patient, in order to provide options for the surgeon.

- 1) **Biodent HEX Cylindrical:** cylindrical external profile, with double “V” thread, with chambers at its apex. Trim with M1.6 / M2 and M2.5 thread. It has a hexagonal-shaped external prosthetic connective platform.
- 2) **Conical Bioneck TRI:** cylindrical external profile, with double “V” thread, with chambers at its apex. Trim with M1.6 / M2 and M2.5 thread. It has a hexagonal-shaped external prosthetic connective platform.
- 3) **Cylindrical Dynamic CMI:** cylindrical external profile, with double trapezoidal thread and cutting chambers. Internal with M1.6 thread. It has a conical-shaped internal prosthetic connective platform.
- 4) **Single Conical CMI:** tapered outer profile with trapezoidal thread. Internal with M1.6 thread. It has a conical-shaped internal prosthetic connective platform.
- 5) **Exakort HI Cylindrical:** cylindrical external profile, with double square thread and cutting chambers. Internal with M1.8 thread (Ø1.8mm). It has an internal prosthetic connective platform in hexagonal shape with conical contact.

CYLINDRICAL BIODENT HEX:

- **Ø 3,3mm NP:** available in lengths: 8.5 – 10.0 – 11.5 – 13.0 – 15.0 – 16.0 and 18.0 mm. M1.6 internal thread. It has self-tapping chambers at its apex. Connective platform with HEX NP prosthetic components.
- **Ø 3,75mm RP:** available in lengths: 8.5 – 10.0 – 11.5 – 13.0 – 15.0 – 16.0 and 18.0 mm. M2 internal thread. It has self-tapping chambers at its apex. Connective platform with HEX RP-UP prosthetic components.
- **Ø 4,0mm RP:** available in lengths: 8.5 – 10.0 – 11.5 – 13.0 – 15.0 – 16.0 and 18.0 mm. M2 internal thread. It has self-tapping chambers at its apex. Connective platform with HEX RP-UP prosthetic components.
- **Ø 5,0mm UP:** available in lengths: 8.5 – 10.0 – 11.5 – 13.0 – 15.0 – 16.0 and 18.0 mm. M2 internal thread. It has self-tapping chambers at its apex. Connective platform with HEX RP-UP prosthetic components.

- **Ø 5,0mm WP:** available in lengths: 8.5 – 10.0 – 11.5 – 13.0 – 15.0 - 16.0 and 18.0mm. M2.5 internal thread. It has self-tapping chambers at its apex. Connective platform with HEX WP prosthetic components.

BIONECK TRI CONICAL:

- **Ø 3,5mm NP:** available in lengths: 8.0 – 10.0 – 11.5 – 13.0 – 15.0 and 16.0mm. M1.8 internal thread. Connective platform with TRI NP prosthetic components.
- **Ø 4,3mm NP:** available in lengths: 8.0 – 10.0 – 11.5 – 13.0 – 15.0 and 16.0mm. M1.8 internal thread. Connective platform with TRI NP prosthetic components.
- **Ø 4,3mm RP:** available in lengths: 8.0 – 10.0 – 11.5 – 13.0 – 15.0 and 16.0mm. M2 internal thread. Connective platform with TRI RP-UP prosthetic components.
- **Ø 5,0 mm UP:** available in lengths: 8.0 – 10.0 – 11.5 – 13.0 – 15.0 and 16.0mm. M2 internal thread. Connective platform with TRI RP-UP prosthetic components.
- **Ø 5,0 mm WP:** available in lengths: 8.0 – 10.0 – 11.5 – 13.0 – 15.0 and 16.0mm. M2 internal thread. Connective platform with TRI WP prosthetic components.

CYLINDRICAL DYNAMIC CMI:

- **Ø 3,0mm:** available in lengths: 10.0 – 11.5 – 13.0 – 15.0mm. M1.6 internal thread. It has self-tapping chambers at its apex. Connective platform with CMI 3.0 prosthetic components.
- **Ø 3,5mm NP:** available in lengths: 8.5 – 10.0 – 11.5 – 13.0 – 15.0 – 16.0 – 18.0mm. M1.6 internal thread. It has self-tapping chambers at its apex. Connective platform with CMI NP prosthetic components.
- **Ø 4,3mm RP:** available in lengths: 8.5 – 10.0 – 11.5 – 13.0 – 15.0 – 16.0 – 18.0mm. M1.6 internal thread. It has self-tapping chambers at its apex. Connective platform with CMI RP prosthetic components.
- **Ø 5,0 mm RP:** available in lengths: 8.5 – 10.0 – 11.5 – 13.0 – 15.0 – 16.0 – 18.0mm. M1.6 internal thread. It has self-tapping chambers at its apex. Connective platform with CMI RP prosthetic components.





SINGULAR CONICAL CMI:

- **Ø 3,5mm NP:** available in lengths: 8.0 – 10.0 – 11.5 – 13.0 – 15.0 and 16.0mm. M1.6 internal thread. Connective platform with CMI NP prosthetic components.
- **Ø 4,3mm RP:** available in lengths: 8.0 – 10.0 – 11.5 – 13.0 – 15.0 and 16.0mm. M1.6 internal thread. Connective platform with CMI RP prosthetic components.
- **Ø 5,0 mm RP:** available in lengths: 8.0 – 10.0 – 11.5 – 13.0 – 15.0 – 16.0mm, internal thread M1.6. Connective platform with CMI RP prosthetic components.





CYLINDRICAL EXAKORT HI:

- **Ø 3,3mm:** available in lengths: 8.0 – 10.0 – 11.5 – 13.0 and 15.0. M1.8 internal thread. It has self-tapping chambers at its apex. Connective platform with HI prosthetic components.
- **Ø 3,8mm:** available in lengths: 8.0 – 10.0 – 11.5 – 13.0 and 15.0. M1.8 internal thread. It has self-tapping chambers at its apex. Connective platform with HI prosthetic components.
- **Ø 4,2mm:** available in lengths: 8.0 – 10.0 – 11.5 – 13.0 and 15.0. M1.8 internal thread. It has self-tapping chambers at its apex. Connective platform with HI prosthetic components.

BIODENT HEX CYLINDRICAL IMPLANT





Platform connective	Platform Diameter	Implant Diameter	length
	Ø3,5mm	Ø3,3mm	8,5mm, 10mm, 11,5mm, 13mm, 15mm, 16mm e 18mm
	Ø4,1mm	Ø3,75mm	8,5mm, 10mm, 11,5mm, 13mm, 15mm, 16mm e 18mm
		Ø4,0mm	8,5mm, 10mm, 11,5mm, 13mm, 15mm, 16mm, 17mm e 18mm
	Ø4,1mm	Ø5,0mm	8,5mm, 10mm, 11,5mm, 13mm, 15mm, 16mm e 18mm
	Ø5,1mm	Ø5,0mm	8,5mm, 10mm, 11,5mm, 13mm, 15mm, 16mm e 18mm

BIONECK TRI CONICAL IMPLANT


Platform connective	Platform Diameter	Implant Diameter	length
	Ø3,5mm	Ø3,75mm	8,0mm, 10mm, 11,5mm, 13mm, 15mm e 16mm
		Ø4,3mm	8,0mm, 10mm, 11,5mm, 13mm, 15mm e 16mm
	Ø4,3mm	Ø4,3mm	8,0mm, 10mm, 11,5mm, 13mm, 15mm e 16mm
	Ø4,3mm	Ø5,0mm	8,0mm, 10mm, 11,5mm, 13mm, 15mm e 16mm
	Ø5,0mm	Ø5,0mm	8,0mm, 10mm, 11,5mm, 13mm, 15mm e 16mm




DYNAMIC CMI CYLINDRICAL IMPLANT



Platform connective	Platform Diameter	Implant Diameter	Interface with the Pillar	length
	Ø3,0mm	Ø3,6mm	Ø2,75mm	8,5mm, 10mm, 11,5mm, 13mm e 15mm
	Ø3,0mm	Ø4,3mm	Ø2,75mm	8,5mm, 10mm, 11,5mm, 13mm e 15mm
	Ø3,0mm	Ø5,0mm	Ø2,75mm	8,5mm, 10mm, 11,5mm, 13mm e 15mm


SINGULAR CONICAL IMPLANTATION CMI



Platform connective	Platform Diameter	Implant Diameter	Interface with the Pillar	length
	Ø3,0mm	Ø3,75mm	Ø2,75mm	8,0mm, 10mm, 11,5mm, 13mm e 16mm
	Ø3,0mm	Ø4,3mm	Ø2,75mm	8,0mm, 10mm, 11,5mm, 13mm e 16mm
	Ø3,0mm	Ø5,0mm	Ø2,75mm	8,0mm, 10mm, 11,5mm, 13mm e 16mm

EXAKORT HI IMPLANT



Platform connective	Platform Diameter	Implant Diameter	length
	Ø3,4mm	Ø3,3mm	8,0mm, 10mm, 11,5mm, 13mm e 15mm
	Ø3,7mm	Ø3,8mm	8,0mm, 10mm, 11,5mm, 13mm e 15mm
	Ø3,7mm	Ø4,2mm	8,0mm, 10mm, 11,5mm, 13mm e 15mm

LIST OF ACCESSORIES INTENDED TO INTEGRATE THE PRODUCT:

DÉRIG Implants contain the accessories described below:

Cover Screw

Each implant is accompanied by its respective Cover Screw, produced in titanium, to be installed over the Implant, in order to protect the internal parts of the Implant, when the Surgeon makes the option of placing the provisional prosthesis after the osseointegration phase. It has a thread at its apex, connecting with the respective implant.

COMPOSITION OF PRODUCTS:

All Dental Implants and Cover Screws are manufactured with Grade 4 Pure Titanium as per ASTM F67 standard.

INDICATION OF USE:

DÉRIG Dental Implants are applied in oral surgery, and are indicated for patients with unitary, partial or total absence of teeth. The implant's primary function is to serve as a supporting pillar to receive the fixed or removable prosthesis, in order to replace the natural tooth root.

DÉRIG Implants are divided into 8 groups, each group being indicated for a region of the dental arch or depending on the bone class, technique or surgical situation appropriate for each patient.

Specific indication of use for each model:

Biodent HEX have a high cutting power and are indicated for single and multiple prostheses in bone types I, II, III and IV. In type I bones, the use of a thread former is indicated, available in the DÉRIG system (not supplied).

Bioneck TRI and have a high compaction power and are indicated for single and multiple prostheses in type III and IV bones.

CMI Singular Conical Implants have a high compaction power and are indicated for single and multiple prostheses in type III and IV bones.

Cylindrical Dynamic CMI Implants have a high compaction power. Models NP 3.5 – RP 4.3 – RP 5.0 are indicated for single and multiple prostheses in type IV cancellous bone. The 3.0 model is indicated for a single prosthesis to replace central, lateral or canine incisor teeth, in bone types I, II, III and IV.

Exakort Implants have a high compacting power and are indicated for single and multiple prostheses in type III and IV bones.

Business model:

Cylindrical Biodent HEX (all models)

Conical Bioneck TRI (all models)

Cylindrical Dynamic CMI (all models)

Conical Single CMI (all models)

Exakort HI Cylindrical (all models)

This product is an integral part of a system and must be used in conjunction with the original Dérig products. The use of products manufactured by third parties in together with Dérig products may jeopardize the product warranty. The user of Dérig products has a duty to determine whether or not any product is suitable for a patient. Dérig does not assume any responsibility, express or implied, and will not be liable for any direct damages, indirect, punitive or otherwise, resulting from or associated with errors in evaluation or professional practice in the use of Dérig products. In cases of doubt, the clinician you should contact Dérig. Since the use of this product is controlled by the professional, this is your responsibility. Dérig does not assume any liability for damages resulting therefrom. Some products described in this Instruction of Use may not be approved, have marketing authorization or be licensed for sale.

PRECAUTIONS AND WARNINGS:

DÉRIG Implants must be installed under controlled surgical conditions. Implants must be surgically installed by a qualified and specialized professional.

The professional must plan the surgery using diagnostic imaging tools (radiographs, tomography exams, etc.) and prepare a surgical plan by selecting the implant(s) most suited to the quantity and quality of bone available to the patient. The use of implants in patients in the growing phase is not recommended.

In order for the implant to be correctly housed and to integrate with the bone structure, high precision is essential in making the bone pocket, using a calibrated and sterile surgical instrument, and the sequence of drills corresponding to the diameter of the implant in the perforation, with rotation adequate and irrigation, thus avoiding thermal trauma and ensuring the successful application of the product.

The **Dental Implant** is sterilized by gamma radiation and is for single use, and its use is contraindicated in case the package has been opened or violated before the moment of

application. The resterilization performed by the professional is contraindicated. PROHIBITED REPROCESSING.

The professional must submit the patient to an oral asepsis before applying the product, thus preventing the implant from coming into contact with any non-sterile substance contaminating the bone store.

The professional must verify the information contained in the product packaging, paying attention to the expiration date and identification of the product.

The professional must pay attention to the torque indicated when applying the product, so as not to damage it. It is advisable not to exceed the maximum insertion torque, as shown in the table, as a guarantee of the integrity of the implant.

Descriptive table of the maximum applied torque:

<i>business model</i>				<i>maximum torque</i>
<i>Cylindrical</i>	<i>Biodent</i>	<i>HEX</i>	<i>NP</i>	<i>35Ncm</i>
<i>Cylindrical</i>	<i>Biodent</i>	<i>HEX</i>	<i>RP</i>	<i>45Ncm</i>
<i>Cylindrical</i>	<i>Biodent</i>	<i>HEX</i>	<i>UP</i>	<i>45Ncm</i>
<i>Cylindrical</i>	<i>Biodent</i>	<i>HEX</i>	<i>WP</i>	<i>45Ncm</i>
<i>Cylindrical</i>	<i>Dynamic</i>	<i>CMI</i>	<i>3,0</i>	<i>25Ncm</i>
<i>Cylindrical</i>	<i>Dynamic</i>	<i>CMI</i>	<i>NP</i>	<i>35Ncm</i>
<i>Cylindrical</i>	<i>Dynamic</i>	<i>CMI</i>	<i>RP</i>	<i>45Ncm</i>
<i>Cylindrical</i>	<i>Dynamic</i>	<i>CMI</i>	<i>RP</i>	<i>45Ncm</i>
<i>Conical</i>	<i>Bioneck</i>	<i>TRI</i>	<i>NP</i>	<i>35Ncm</i>
<i>Conical</i>	<i>Bioneck</i>	<i>TRI</i>	<i>RP</i>	<i>45Ncm</i>
<i>Conical</i>	<i>Bioneck</i>	<i>TRI</i>	<i>UP</i>	<i>45Ncm</i>
<i>Conical</i>	<i>Bioneck</i>	<i>TRI</i>	<i>WP</i>	<i>45Ncm</i>
<i>Conical</i>	<i>Singular</i>	<i>CMI</i>	<i>NP</i>	<i>35Ncm</i>
<i>Conical</i>	<i>Singular</i>	<i>CMI</i>	<i>RP</i>	<i>45Ncm</i>
<i>Conical</i>	<i>Singular</i>	<i>CMI</i>	<i>RP</i>	<i>45Ncm</i>
<i>Cylindrical</i>	<i>Exakort</i>	<i>HI</i>	<i>NP</i>	<i>45Ncm</i>

Cover screws (all models),
Maximum torque 10Ncm
See accessories

It is advisable that the products be organized in such a way that the information and expiration date contained on the packaging are visible.

The implants are identified in accordance with current regulations, and the identification label provided inside the product packaging must be attached to the patient's medical record.

The professional must inform the patient about the proper form of hygiene, the need for periodic post-surgical follow-up.

As precautions in addition to the above precautions, it indicates whether, when reaching the midpoint of the osteotomy, to stop and take an X-ray to perform a new assessment and confirmation of the planning.

CONTRAINDICATIONS:

The application of implants in patients with vascular disorders, uncontrolled diabetes or other metabolic or systemic diseases that affect tissue healing, coagulation disorders, treatment with anticoagulants, metabolic bone disease, patients not psychologically prepared to undergo rehabilitation is contraindicated total oral, inadequate oral hygiene, insufficient spaces between the arches, non-treatable occlusion/joint problems, insufficient bone height and/or width, active intraoral infection, and in cases of alcohol and tobacco abuse. Temporary contraindications include: chemotherapy and radiation therapy, as well as chronic periodontal inflammation or insufficient soft tissue coverage.

STORAGE, TRANSPORTATION, PRESERVATION AND HANDLING:

DÉRIG implants must be stored and/or transported in their original packaging and kept in a dry place at a temperature of 25°C \pm 2°C and maximum humidity of 70%. It is advisable that the products be organized in such a way that the information and expiration date contained on the packaging are visible.

DÉRIG implants are identified in accordance with current regulations, and the identification label provided inside the product packaging must be attached to the patient's medical record.

DISCARD:

All products and materials used in Dental Implant Installation surgery can put the health of those who handle them at risk after use.

Before disposing of them, we recommend that you consult and comply with current legislation in your region.

The legislation in force in Brazil regarding disposal to be consulted is RDC/Anvisa No. 222, of 28/03/2018, or whichever replaces it.

VALIDITY AND LOT:

Date of manufacture, expiration and batch, see packaging.

STERILIZATION:

The implant is supplied STERILE. The DÉRIG osseointegrated implant system is sterilized by gamma rays with a load of 25 kGy to 40kGy, thus ensuring the sterility of the product, except in cases of violation of the packaging and products that are out of date.

CONTENTS:

They are provided with the following content:

- 01 dental implant;
- 01 Cover Screw;
- 03 Batch Identification Tags;

HANDLING INSTRUCTION:

Check that the dimension matches your surgical plan. Check expiration date. Open the cardboard shipping container. Check that the sterile inner packaging is with the blister perfectly sealed. Discard the product if the packaging is damaged or out of date. Affix the separate labels to the patient's record. Open the blister only when inserting the implant.

Start drilling with the sequence of cutters corresponding to the implant.

Ask your assistant to remove the capsule from the blister. Take the bottle and place it in the crib. Open the bottle by unscrewing the cap. Remove the cover screw holder to expose the implant. Capture the implant with the appropriate insertion key. Insert the implant into the newly drilled cavity. 20RPM maximum insertion speed. If done manually, use the maximum torque according to the table. Carefully open the cover screw holder. Catch the cover screw with the proper wrench. Thread it to the implant.

ADVERSE EFFECTS:

If the technique used is not adequate and the patient is not submitted to the indicated exams, the final result of the application of the product may be unsatisfactory, as well as causing the patient an unnecessary resorption of the bone structure.

The surgical process can bring adverse effects in the region where it was applied, such as: chronic pain, edema, hematoma, hemorrhage, swelling, dehiscence, short sensitivity duration, tissue reaction, infection, difficulty speaking, numbness of the labial region and lower jaw in a lower jaw surgery and numbness of the lateral tissue of the nose in an upper jaw surgery. Dormancy cases are temporary effects, in very rare cases permanent numbness has already occurred.

REUSE

The Dérig Implant is provided for single use, reprocessing as stated on the identification label is prohibited.

Reuse of the product can lead to patient contamination since sterilization is valid only until the opening of the package

WARNING

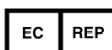
**Dental product, to be used by licensed professionals to apply the technique.
Supplied STERILE by Gamma Rays.**



Dérig Ind. e Com. de Materiais Médico-Odontológicos Ltda.
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Technician Responsible: Edson Meronho – **CREA-SP nº 5063423447**

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Símbolo/symbol	Português	English
	Consulte as instruções de uso ou consulte as instruções de uso eletrônicas	<i>Consult instructions for use or consult electronic instructions for use</i>
	Proibido reutilizar	<i>Do not re-use</i>
	Produto não-estéril	<i>Do not sterile</i>
	Número de lote	<i>Batch number</i>
	Código referência	<i>Catalogue number</i>
	Representante Autorizado na Comunidade Europeia	<i>Authorized representative in the European Community</i>
	Data de Fabricação	<i>Date of manufacture</i>
	Fabricante	<i>Manufacturer</i>
	País do Fabricante	<i>Country of manufacture</i>
	Manter seco	<i>Keep Dry</i>
	Não use se a embalagem estiver danificada e consulte as instruções de uso	<i>Do not use if package is damaged and consult instructions for use</i>
	Validade	<i>Use by date</i>
	Manter ao abrigo de luz solar	<i>Keep away from sunlight</i>
	Marcação CE	<i>CE Mark</i>

MD	Produto Médico/Dipositivo Médico	<i>Medical Device</i>
SS	Não-pirôgênico	<i>Non-pyrogenic</i>