Instruction for use
Ti Components

TECHNICAL NAME : DENTAL IMPLANT COMPONENTS

TRADE NAME: Ti COMPONENT

Profile Abutment HEX NP C1
Profile Abutment HEX NP C2
Profile Abutment HEX NP C3
Profile Abutment HEX NP C4
Profile Abutment HEX RP-UP C1
Profile Abutment HEX RP-UP C2
Profile Abutment HEX RP-UP C3
Profile Abutment HEX RP-UP C4
Profile Abutment TRI NP C0,5
Profile Abutment TRI NP C1
Profile Abutment TRI NP C2
Profile Abutment TRI NP C3
Profile Abutment TRI NP C4
Profile Abutment TRI RP-UP C0,5
Profile Abutment TRI RP-UP C1
Profile Abutment TRI RP-UP C2
Profile Abutment TRI RP-UP C3
Profile Abutment TRI RP-UP C4
Fixing Screw HEX NP / hex 1,2
Fixing Screw HEX RP-UP / hex 1,2
Fixing Screw HEX RP-UP / grip
Fixing Screw TRI NP / hex 1,2
Fixing Screw TRI NP / grip
Fixing Screw TRI RP-UP-WP / hex 1,2
Fixing Screw TRI RP-UP-WP / grip
Fixing Screw BRK NP / hex 1,2
Fixing Screw BRK NP/grip
Esthetic Abutment HEX RP-UP C1
Esthetic Abutment HEX RP-UP C2
Esthetic Abutment HEX RP-UP C3
Esthetic Abutment TRI NP C0,5
Esthetic Abutment TRI NP C1
Esthetic Abutment TRI NP C2
Esthetic Abutment TRI NP C3
Esthetic Abutment TRI RP-UP C0,5
Esthetic Abutment TRI RP-UP C1
Esthetic Abutment TRI RP-UP C2

Esthetic Abutment TRI RP-UP C3
Esthetic Abutment 15° HEX NP C1
Esthetic Abutment 15° HEX NP C2
Esthetic Abutment 15° HEX NP C3
Esthetic Abutment 15° HEX RP-UP C1
Esthetic Abutment 15° HEX RP-UP C2
Esthetic Abutment 15° HEX RP-UP C3
Esthetic Abutment 15° TRI NP C0,5
Esthetic Abutment 15° TRI NP C1
Esthetic Abutment 15° TRI NP C2
Esthetic Abutment 15° TRI RP-UP C1
Esthetic Abutment 15° TRI RP-UP C2
Temporary Abutment HEX NP R
Temporary Abutment HEX RP-UP R
Temporary Abutment TRI NP R
Temporary Abutment TRI RP-UP R
Temporary Abutment HEX NP AR
Temporary Abutment HEX RP-UP AR
Temporary Abutment TRI NP AR
Temporary Abutment TRI RP-UP AR
Temporary Coping MPC
Coping Screw MPC / hex 1,2
Coping Screw MPC / grip
Impression Copings HEX NP Open Tray / hex 1,2
Impression Copings HEX RP-UP Open Tray / hex 1,2
Impression Copings TRI NP Open Tray / hex 1,2
Impression Copings TRI RP-UP Open Tray / hex 1,2
Impression Copings MPC Open Tray / hex 1,2
Impression Copings HEX NP Closed Tray / hex 1,2
Impression Copings HEX RP-UP Closed Tray / hex 1,2
Impression Copings TRI NP Closed Tray / hex 1,2
Impression Copings TRI RP-UP Closed Tray / hex 1,2
Healing Cap MPC / hex 1,2

PRODUCT DESCRIPTION:

The **DERIG Abutments** are provided in a single part, manufactured as from turning of 6Al 4V ELI Alloyed Titanium bars, in compliance with rule ASTM F136.
The **DÉRIG Abutment**, has a cylindrical format and its end is connected to the DÉRIGImplant (HEX, TRI)
The DÉRIG Abutments are of SINGLE USE, and REPROCESSING IS PROHIBITED.
They are supplied UNSTERILE.

PRODUCT COMPOSITION:

The Ti Components are manufactured with Titanium raw material in compliance with ASTM F136, and according to the national and international standards.

PRECAUTIONS AND RECOMENDATIONS:

The Ti DÉRIG Components should be prepared in laboratory, using the adequate tools and equipment.
The prostheses prepared on the components should be installed by qualifiedprofessionals and with experience.
The components are provided unsterile and should be sterilized by the professionalsprior to their use. They are of unique use, and their reprocessing is forbidden.
The professional should plan and prepare a prosthetic execution plan.
The professional should submit the patient to mouth disinfection prior to application ofthe product.
The professional should inform the patient as related to the adequate oral hygiene andthe need of a periodic post-installation follow-up
Follow the toque indication in the table covering the Fixing Screws, MPC Coping Screw, PC Coping Screw and Transfer Screw.
Follow the indication table covering connectivity between the Ti Component.

CONTRAINDICATIONS

It is recommended that the prostheses prepared on the Ti DÉRIG components should not be installed on patients with chronic periodontal inflammation, patients not preparedto be submitted to oral rehabilitation, inadequate oral hygiene and inadequate parafunctional habits such as: bruxism, non treatable occlusion/articulation problems and active intraoral infection. In case of immediate loading, the primary stability of the implant should be checked.

HANDLING INSTRUCTION

Check if the sizes correspond to the prosthetic plan. Open the pack. Stick the separate labels on the patient medical record. Prepare the prosthesis according to the prostheticplan. Install the prosthesis on the implant or on the abutment, using the adequate tools and in case of fixing by a screw, *use the indicated torque*.

CONTENT

The Ti Components are packed individually in a packing comprising a blister, paper of surgical degree and external cartridge. They are supplied with the following content:

- Ti Component (1 unit);
- Accessory when applicable (01 unit)
- 03 batch identification labels in polyester with adhesive glue for the medical record;
- Instruction for use available in : www.derig.com.br

INDICATION OF USE

The Ti Components are recommended for patients with unit, partial or total absence of teeth. The primary function of the Component is to actuate as a support abutment to receive the fixed or removable prosthesis.

Esthetic and Profile Abutments are recommended for installation and fixing by means of a screw on the implants, with the objective to support a unit or multiple prostheses.

Temporary Abutments are recommended for support to a Temporary prosthesis,during Prepare of the final prosthesis.

The protection covers (healing) are indicated to be fixed on the abutments, to assure their integrity during prepare of the prosthesis.

The screws are indicated for fixing of abutments, Temporary and Transferors.

Impression Copings (Open tray) are indicated to be fixed to the implant or to the prosthetic component to be molded in direct molding techniques, thus transferring the accurate position of the implant or of the prosthetic component in relation to theadjacent teeth, for the laboratorial model.

Impression Copings (Closed tray) are indicated to be fixed to the implant or to the prosthetic component to be molded in indirect molding techniques, thus transferring theaccurate position of the implant or of the prosthetic component in relation to theadjacent teeth, for the laboratorial model.

PROFILE ABUTMENT

- HEX NP Profile Abutment, available in heights: 1.0, 2.0, 3.0, and 4.0mm - Abutment with platform connective with HEX NP implants.
- HEX RP-UP Profile Abutment, available in heights: 1.0, 2.0, 3.0, and 4.0mm.Abutment with platform connective the HEX RP and HEX UP implants.
- TRI NP Profile Abutment, available in heights: 0.5, 1.0, 2.0, 3.0, and 4.0mm. - Abutment with platform connective with TRI NP implants.
- TRI RP-UP Profile Abutment, available in heights: 1.0, 2.0, 3.0, and 4.0mm. - Abutment with platform connective with TRI RP-UP implants.

FIXING SCREW

The Fixing Screw is manufactured in 6Al 4V ELI Alloyed Titanium in compliance withrule ASTM F136.

- HEX NP Fixing Screw, a screw with M1.6mm thread that connects with HEXNP implants, and hexagonal DERIG prosthetic wrench of 1.20mm and GRIP.
- HEX RP-UP Fixing Screw, a screw with M2,0mm thread that connects with HEX NP implants, and hexagonal DERIG prosthetic wrench of 1.20mm and GRIP.
- TRI NP Fixing Screw, a screw with M1.8mm thread that connects with HEX NP implants, and hexagonal DERIG prosthetic wrench of 1.20mm and GRIP.
- TRI RP-UP-WP Fixing Screw, a screw with M2,0mm thread that connects with TRI.
- BRK NP Fixing Screw, a screw with M1.6mm thread that connects with HEX NP implants, and hexagonal DERIG prosthetic wrench of 1.20mm and GRIP.

15º PREPARE ABUTMENT

15º HEX NP Profile Abutment, available in the belt heights: 2.0mm and 3.0mm.Abutment with platform connective with HEX NP implants.
15º HEX RP-UP Profile Abutment, available in the belt heights: 3.0mm and4.0mm. Abutment with platform connective the HEX RP and HEX UP implants.
15º TRI NP Profile Abutment, available in the belt heights: 3.0mm and 4.0mm.Abutment with platform connective with TRI NP implants.
15º TRI RP-UP Profile Abutment, available in the belt heights: 3.0mm and 4.0mm. Abutment with platform connective with TRI RP-UP implants.

ESTHETIC ABUTMENT

The Esthetic Abutment is constituted by a cylindrical abutment, manufactured in6Al 4V ELI Alloyed Titanium, in compliance with rule ASTM F136.

HEX NP Esthetic Abutment, available in heights: 1.0, 2.0, and 3.0mm. Abutment with platform connective with HEX NP implants.
HEX RP-UP Esthetic Abutment, available in heights: 1.0, 2.0, and 3.0mm.Abutment with platform connective the HEX RP and HEX UP implants.
TRI NP Esthetic Abutment, available in heights: 0.5, 1.0, 1.5, 2.0 and 3.0mm.Abutment with platform connective with TRI NP implants.
TRI RP-UP Esthetic Abutment, available in heights: 0.5, 1.0, 1.5, 2.0 and 3.0mm.Abutment with platform connective with TRI RP-UP implants.

15º ESTHETIC ABUTMENT

The 15º Esthetic Abutment is constituted by a cylindrical abutment, manufactured in6Al 4V ELI Alloyed Titanium, in compliance with rule ASTM F136.
15º HEX NP Esthetic Abutment, available in heights: 1.0, 2.0mm.
Abutment with platform connective with HEX NP implants.
15º HEX RP-UP Esthetic Abutment, available in heights: 2.0 and3.0mm. Abutment with platform connective the HEX RP and HEX UP implants.
15º TRI NP Esthetic Abutment, available in heights: 0.5, 1.0, 2.0 mm.
Abutment with platform connective with TRI NP implants.
15º TRI RP-UP Esthetic Abutment, available in heights: 1.0, 2.0mm.
Abutment with platform connective with TRI RP-UP implants.

TEMPORARY ABUTMENT:

The **DERIG Temporary Abutments** are provided in a single part, manufactured as from turning of 6Al 4V ELI Alloyed Titanium bars, in compliance with rule ASTM F136.
The **DÉRIG Temporary Abutment**, has a cylindrical format and its end is connected to the DÉRIG Implant (HEX, TRI)
The Temporary Abutment can be **Rotational**, represented by the letter **"R"**, indicated for multiple prostheses or **Anti-rotational**, represented by the letter "**AC"**, indicated for unit prosthesis.

TEMPORARY ABUTMENT "R"

HEX NP R Temporary Abutment, an abutment with platform connective with HEXNP implants.
HEX RP-UP R Temporary Abutment, an abutment with platform connective withHEX RP and HEX UP implants.
TRI NP R Temporary Abutment, an abutment with platform connective with TRINP implants.
TRI RP-UP R Temporary Abutment, an abutment with platform connective withTRI RP implants.

TEMPORARY ABUTMENT "AR"

HEX NP AR Temporary Abutment, an abutment with platform connectivewith HEX NP implants.
HEX RP/UP AR Temporary Abutment, an abutment with platform connectivewith HEX RP/UP implants.

TRI NP AR Temporary Abutment, an abutment with platform connective with TRINP implants.
TRI RP/UP AR Temporary Abutment, an abutment with platform connective withTRI RP/UP implants.

TEMPORARY COPING "MPC"

Abutment with rotational platform, connective with Conical Mini AbutmentComponent.

COPING SCREW:

MPC Coping Screw, a screw with thread of M1.4mm, adapts in Conical Mini Abutment Component, connects with the hexagonal DERIG prosthetic wrench of 1.20mm and GRIP.

PROTECTION COVER (Healing Cap)

The DÉRIG Protection Cover is a protection that is installed on the Conical Mini Abutments and on the Conical Abutments while the surgeon is preparing the Temporary or Final prosthesis, in order to protect the internal part of the residue-abutments.
The Protection Cover is constituted by a single cylindrical part manufactured in 6 Al 4 VELI Alloyed Titanium, in compliance with rule ASTM F136.
MPC Protection Cover, connective with Conical Mini Abutment and hexagonal DERIG Prosthetic Wrench of 1.20mm and GRIP.

TRI Models

Fixing screw for TRI models
TRI NP M 1.8mm thread
TRI RP-UP M 2,0mmthread

HEX Models

Fixing screw for HEX models
HEX NP M 1.8mm thread
HEX RP-UP M 2,0mm thread

FIXING SCREW

The Fixing Screw is supplied in a single part, manufactured as from turning of 6Al 4V ELI Alloyed Titanium, in compliance with rule ASTM F136, and its objective is to fix the Derig Abutments [all models to Derig implants (all models)].
For the Fixing Screw models, a torque of 35 Ncm is applied and for the Transfer Screws 15 Ncm.

Torque indication table for Screws	
Fixing Screw (HEX-TRI)	*35 Ncm*
Transfer MA Screw (HEX-TRI)	*10Ncm*
Transfer MF Screw (HEX-TRI)	*10Ncm*
MPC Coping Screw	*15 Ncm*
PC Coping Screw	*15 Ncm*

"*Note 1*
The different connection wrenches, connective platform and other variations donot interfere in torque indication.

"*Note 2*
For application of the given torque, use the Universal Torquemeter, not suppliedwith the product, available in the Full Prosthetic Kit, manufactured by Derig.

STORAGE, TRANSPORTATION, PRESERVATION AND MANIPULATION

The Ti DERIG Components should be stored and/or in their original packing and maintained in dry location and at temperature of 25ºC +/- 2ºC and humidity 70%.
We recommend that the products be organized in such a manner that the information indicated in the packing can be visible.
The Ti DERIG Components are identified according to the current rules.
The transportation should be in original packaging
The identification label provided inside the product packing should be attached to the patient medical record.

EXPIRATION DATE AND LOT

Manufacturing date, validity and lot, see packing.

DISPOSAL

All the products and material used in the dental implant installation surgery can put at rick the health of those that handled them after their usage.
Prior to disposal, we recommend checking and complying with the current legislation.

STERILIZATION

Label the sterilization pouch with information necessary to identify the device (for example, the product name with number and lot/batch number (if applicable)).
Place the sealed sterilization pouch into the autoclave/sterilizer.
Sterilize the device applying the parameters below:

Cycle	Temperature	Time	Drying Time (In Chamber)
Sterilization	132°C 270°F)	4 minutes	30 minutes

Note: Autoclave/sterilizer design and performance can affect the efficacy of the sterilization process. Healthcare facilities should therefore validate the processes that they use, employing the actual equipment and operators that routinely process the devices.

ADVERSE EFFECTS

If the technique used by the professional is not adequate, the esthetic may be jeopardized, as well as the correct operation. Mainly occlusion problems can occur, overloading in an unequal manner the dental arch.

RE-USE

The Dérig Components are supplied for a unique use, thus, the re-processing is prohibited and as informed in its identification label.
Reuse of the product can result in contamination of the patient.

ATTENTION

Product for dental use, to be used only by professionals qualified for technical application. Supplied UNSTERILE.

FORBIDDEN TO REPROCESS.

If you need this printed IFU, you can get it from our European representative at no charge. Details of our European representative are at the end of this document.

For eventual submission of paper IFU, data can be requested and processed with your consent according to current legal requirements

Instructions for Use for the European Market are provided in English (EN)

The content of the paper ifu has the same content of this electronic IFU

If you request the Instruction for Use in paper, you will receive by seven days after your request.

Dérig Ind. e Com. de Materiais Médico-Odontológicos Ltda.

Address: Rua Lapa, 479 - CEP 06419-020 - Barueri - São Paulo

Phone: +55 0800 777 1991 | 11 4161 8090

www.derig.com.br - derig@derig.com.br

BR

Brazil

Technician Responsible:

Edson Aparecido Meronho

CREA-SP nº5063423447 (register)

ANVISA Register number

80165910010

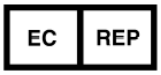
EC REP

Exaktus – Material de Reabilitação Oral

Located at: Rua Laborim 68, 4430-128 Vila Nova de Gaia, Portugal

(+351) 224 068 098

CE 2460

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

MD	Produto Médico/Dipositivo Médico	Medical Device
	Não-pirogênico	Non-pyrogenic