

## INSTRUCTIONS FOR USE

### IMPLANT RETENTION SYSTEM DUALOCK®

Please carefully read the instructions below to guarantee the correct use of the product with complete safety.

In compliance with Directive 93/42/EEC and the later modification to Directive 2007/47/EEC, the required information is provided for efficient use of EM EXACT, S.A. manufactured products

#### STORAGE AND HANDLING

- All products manufactured by EM EXACT, S.A., should be stored at temperatures of between 15-25°C and a humidity of 50-60%. Products should be protected from direct sunlight and any artificial ultraviolet light. They should be protected against acids and bases. The product comes perfectly packaged and heat-sealed. Any default in this packaging could lead to a loss of decontamination and disinfection properties, hence it is recommended not to be used.
- Under no circumstances should material be extracted from the original packaging and handled without being used.
- EM EXACT, S.A. manufactured products are not sterile. It is therefore recommended to sterilize products before use, following the methods indicated in the corresponding section.

#### INDICATION

- The **DUALOCK®** retention system is appropriate for use with total or partial overdentures on implants placed on both the jaw and maxilla. Compatible for all catalog specific connections.
- The system is indicated to be integrated in prostheses with inclination of up to 15 degrees in unitary fixture and in divergences between two implants of up to 30 degrees. For those cases in which they have greater inclinations, the use of the angled pillars at 15° is recommended.

## CONTRAINDICATIONS

- Contraindicated the use of the products in case of patients with conditions that rule out the use of surgery for the placement of dental implants.
- The use of the **DUALOCK**<sup>®</sup> retention system is not recommended for patients who need a completely rigid connection.

## STERILIZATION METHODS

- **DUALOCK**<sup>®</sup> products are presented not sterile. It is recommended to follow the method of sterilization by moist heat (autoclave), for the pillar together with the positioner. For male parts (retainers) of Peek and Nylon can be sterilized / disinfected with a liquid chemical sterilizing agent.

- **Sterilization method Pillar and Positioner:**

Previously it will be necessary to extract the abutment together with the positioner out of the capsule, insert them in a bag, suitable for autoclaving and continue with the method described below.

It is the method most commonly used in dental clinics and laboratories. Sterilization occurs through a physical agent, moist heat, which produces denaturation and protein coagulation. These effects are mainly due to two reasons:

Water is a highly reactive chemical species. Many biological structures (DNA, RNA, proteins, etc.) are produced by reactions that eliminate water. Therefore, reverse reactions could damage the cell as a result of the production of toxic products. The secondary and tertiary structures of proteins are also stabilized, through intermolecular bonding forces of hydrogen, which can be replaced and broken down by water at high temperatures.

The water steam has a heat transfer coefficient much higher than air. Therefore, damp materials conduct heat much quicker than dry materials, owing to the energy released during condensation.

The autoclave is the most widely used apparatus for temperatures over 100°C. A temperature of 121°C (overpressure atmosphere), with an exposure time over 15 minutes, following the recommendations of the autoclave manufacturer, is used to destroy spore-forming organisms.

Pressure [atm]	Temperature [°C]			
	Complete discharge of air	2/3 discharge of air	1/2 discharge of air	Without discharge of air
1/3	109	100	90	72
2/3	115	109	100	90
1	121	115	109	100
4/3	126	121	115	109
5/3	130	126	121	115
2	133	130	126	121

Influence of incomplete discharge of air at the temperature of the autoclave

### Advantages

- Quick heating and penetration
- Quick destruction of bacteria and spores
- Leaves no toxic residues
- Low deterioration of exposed material
- Economical

### Disadvantages

- Solutions which form emulsions with water cannot be sterilized
- Corrosive on certain metal instruments

- **Method of sterilization Peek and Nylon retainers:**










The male parts (retainers) can be sterilized / disinfected

with a liquid chemical sterilizing agent. To guarantee the sterilization / disinfection of the male parts of Peek and Nylon (all microorganisms are eliminated, including the spores of the bacteria Clostridium sporogenes and Bacillus subtilis), they must soak in the liquid sterilizing agent for at least 3 hours at room temperature.

## RISK DERIVED DURING THE USE OF THE PRODUCT

- There is a risk of aspiration or ingestion of the products, when they are used intraorally, so the appropriate measures must be taken to avoid it.
- There is the possibility of loosening of the attachments, so maintenance must be carried out and the revisions proposed by the doctor / dentist must be attended.
- There are risks presented by allergy to the materials that may appear after the use of the product, in which case the appropriate measures should be taken that could be the immediate withdrawal of the product in the patient.

## SYMBOLY AND DESCRIPTION

Symbol	Description
	Date of manufacture
	Date of Expiry
	Single use. Do not reuse
	Batch Number
	Article reference number
	Attention! See instructions for use
	Details of the manufacture
	Non-sterile product
	MDD CE marking

## MANUFACTURE AND DISTRIBUTION

- All the products of **DUALOCK®** series are manufactured by EM EXACT, S.A. and distributed exclusively by Futuracam

Soluciones Dentales S.L.

## PRECAUTION







- EM EXACT, S.A. products are intended for use by qualified health professionals (Dental Technicians, Doctors and Dentists). Safety and efficiency of supplied EM EXACT, S.A. products, both screws, abutments and other surgical and prosthetic dental accessories are only guaranteed when they are used by qualified professionals.
- Qualified health professionals (Dental Technicians, Doctors and Dentists) are recommended to regularly check for possible changes in the functioning of the product every 6 months.
- EM EXACT, S.A. products are for single use before the expiry date, as indicated on the label. If the product is withdrawn from the patient, it should be disposed of, as it could have been in contact with biological materials of the patient (blood, tissue, etc.), and traces of these could pass to another patient, if it is reused without proper cleaning and disinfection.

## RECOMMENDED TORQUE GUIDE

- The recommended tightening torque for the Threaded Pillars is 30 N.cm. For those implants whose insertion torque has been less than 30 N.cm, the tightening of the Threaded Pillars must be done by hand.

## MATERIAL GUIDE

- Below is a table with the materials used that make up the different **DUALOCK®** Kits. :

3D Image	Description	Material
	Compatible abutments for Implant Systems	Titanium Grade 5
	Housing <b>DUALOCK®</b>	Titanium Grade 5
	Space maintainer <b>DUALOCK®</b>	White Silicone
	Positioner <b>DUALOCK®</b>	Polyacetal
	PEEK Retentions male	Polyether Ether Ketone (PEEK)
	Nylon Retentions male	Polynil (Nylon)

## FORCES GUIDE OF MALE CAPS

- Below is a table with the retaining forces of the buttons that make up the different **DUALOCK®** Kits:

Description	Retention Force	Material
<b>Z Black</b>	1-1,5 lbs.	Peek
<b>Z Red</b>	2,5-3 lbs.	Peek
<b>Z White</b>	4,5-5 lbs.	Peek
<b>N Black</b>	2 lbs.	Nylon
<b>N Red Ang.</b>	1-1,5 lbs.	Nylon
<b>N Blue</b>	1,5 lbs.	Nylon
<b>N Pink</b>	3 lbs.	Nylon
<b>N White</b>	5 lbs.	Nylon
<b>N Orange Ang.</b>	3 lbs.	Nylon
<b>N Green Ang.</b>	4 lbs.	Nylon
<b>P Black</b>	0,8-1 lbs.	Peek
<b>P Red</b>	1,6-1,8 lbs.	Peek
<b>P Blue</b>	2,6-2,8 lbs.	Peek
<b>P White</b>	4,4-4,8 lbs.	Peek