


I GENERAL INSTRUCTIONS

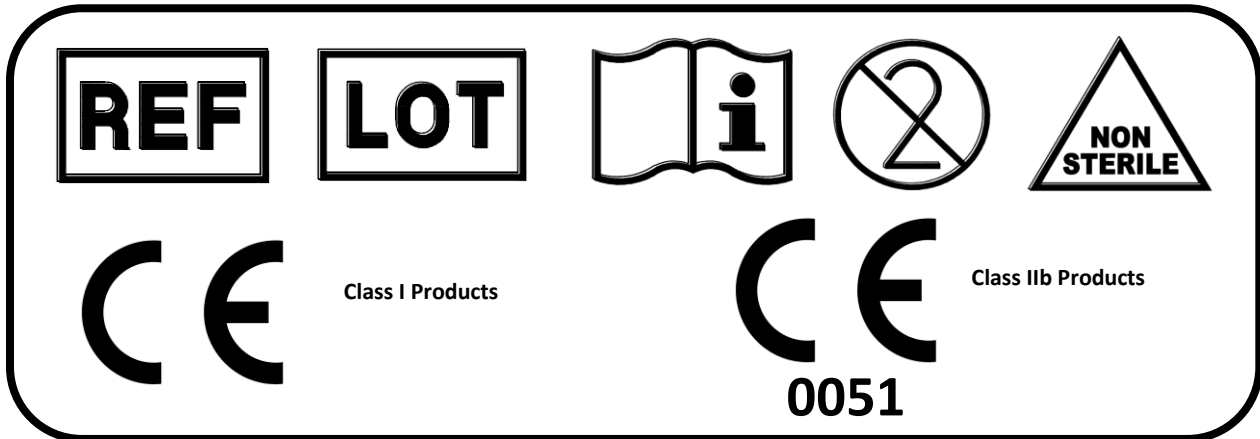
1. MANUFACTURER INFORMATION

All the products that commercialize and distribute Implant Prótesis Dental 2004 S.L. have been manufactured in the facilities of Implant Prótesis Dental 2004.

The website of the company is www.ipd2004.com. The contact telephone number is 93 278 84 91.

 The factory is located in Cami del mig 71, Bajos 08302 Mataró, Barcelona.

2. PRODUCT INFORMATION



3. STORAGE AND HANDLING

All products manufactured by Implant Prótesis Dental 2004 SLU should be stored at a temperature between 15-25 ° C and 40-60% humidity. The products must be kept away from direct sunlight and any artificial ultraviolet light. The product is well packaged and sealed. A defect on the packaging may involve the loss of the properties of decontamination and disinfection, it is recommended to avoid their use. The material must not be unpacked and handled if it is not going to be immediately used.

Implant Prótesis Dental 2004 products are not sterile. It is recommended sterilization before use, following the methods proposed in section 4.

4. WARNING AND CONTRAINDICATIONS

The reuse of single-use products carries a possible deterioration of its characteristics, which implies the risk of infection of the tissues and /or deterioration of the patient's health.

There is a contraindication to the use of the products for patients with conditions that rule out the use of surgery for placement of dental implants. Check the integrity of the packaging, and do not use in case of alteration.

5. RISK ASSOCIATED TO THE USE OF THE PRODUCTS

There is a risk of aspiration or ingestion of the products when used intra-orally, so that appropriate measures be taken to prevent it.

6. CAUTION

Items supplied Implant Prótesis Dental 2004 SLU are intended to be used by qualified health professionals (dental technicians, doctors and dentists).

The safety and efficacy of the products supplied by Implant Prótesis Dental 2004, is guaranteed only when they are used by trained professionals.

7. STERILIZATION METHODS

ALL PRODUCTS ARE SUPPLIED NON STERILE. For sterilization is recommended autoclave at 134 ° C for five minutes or fifteen minutes at 121 ° C (see UNE-EN ISO 17665-1:2007). Autoclave is the most commonly used method in clinics and dental laboratories. Sterilization is produced by a physical agent, moist heat, which causes protein denaturation and coagulation. These effects are mainly due to two reasons:

- Water is a very reactive chemical and many biological structures (DNA, RNA, proteins, etc.) are produced by reactions that remove water. Therefore, reverse reactions may damage the cell to cause the production of toxic products. Furthermore, the secondary and tertiary structures of proteins are stabilized by intermolecular hydrogen bridge bonds which can be broken and replaced by water at high temperatures.

- Water steam has a much higher heat transfer coefficient than air. Wet materials which conduct heat more faster than dry materials, due to the energy released during condensation.

Presión	Temperatura [°C]			
	Descarga completa del aire	Descarga de 2/3 del aire	Descarga de 1/2 del aire	Sin descarga del aire
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

Tabla 1: *Influence of incomplete air discharge on autoclave temperature*

The autoclave is the device most commonly used for temperatures above 100 ° C. A temperature of 121 ° C (atmosphere pressure) with an exposure time greater than 15 minutes serves to destroy spore forming organisms.


















7.1. Advantages

- Fast heating and penetration
- Destruction of bacteria and spores in a short time
- Does not leave toxic waste
- Low deterioration of exposed material
- Económic

7.2. Disadvantages

- It does not allow to sterilize solutions that form emulsions with water
- It is corrosive to certain metallic instruments

8. LABELING SYMBOLS: ISO 15223-1:2012

ISO 15223 Symbology	Description	IPD Symbology	Description
	Manufacturing date		Recommended torque (N • cm) for screw
	Manufacturer		Torx
	Expiring date		Unigrip
	Do not reuse		Hex (Includes the hex size)
	Batch number		Square drive
	Read instructions for use		Cross drive
	Check instructions for use		TPA Screw
	CE marking, including the number of notify body		
	Product Reference		
	Non Sterile Product		

II SPECIFIC INSTRUCTION FOR USE

1. **CASTABLES**

Made of Delrin plastic (no waste). Observe the following precautions:

- Use wax to create a sufficient gap around the abutment in order to compensate the higher expansion coefficient of the castable material.
- Screw smoothly to avoid damage.
- Create shapes favoring the filling of cavities and prevent bubbling.
- Use materials for casting with high fluidity.

2. **ANALOG**

Made of stainless steel AISI-303. For use as a conventional analog must secure a sufficient fixing parts anti-twist and anti-stripping. Verify the compatibility of the connection, in type and size, between the analogue and the prosthetic element prior to tightening. Do not reuse.

3. **HEALING ABUTMENT**

Made of Titanium grade V. We recommend a gentle hand tightening. The height of this element will be selected to ensures its correct function and prevents transmission of stresses.

4. **INTERFACE ABUTMENT**

Verify the compatibility of the connection, in type and size, between the interface and the implant. Damage in the connection area of the implant must be avoided. An X-ray in the perpendicular axis to the union interface-implant is recommended in order to ensure the correct adjustment.

5. **TITANIUM ABUTMENT**

Verify the compatibility of the connection, in type and size, between the titanium abutment and the implant. Damage in the connection area of the implant must be avoided. An X-ray in the perpendicular axis to the union interface-implant is recommended in order to ensure the correct adjustment.

6. **Co-Cr CASTABLE ABUTMENT**

You need to check compatibility with the implant model you are joining. It should be avoided to damage its area of connection to the implant in the case of carving or machining. The ceramic used with this alloy should have a coefficient of expansion of 14.1×10^{-6} at 500°C or approximate. A pottery far below could give a poor fit, and far above, a break of the same.

7. **IMPRESION COPING**

Are provided for use in open or closed trays, with or without their specific screws. Prior to use, ensure cleanliness of the implant connection seat. Any dirt could affect the subsequent alignment of the prosthesis. Verify the compatibility of the connection, in type and size, between the impression coping and the implant.

8. **SCREWS**

Made of Titanium. For fixing on prosthetic implant. It is imperative the strict compliance with the following conditions:

- For screwing or unscrewing use the appropriate screwdriver.
- The screwdriver must be positioned on the longitudinal axis of the joint prosthesis / implant.
- Both for the first fitting a prosthesis, as for future revisions, new screws should be used.
- For immediate load prosthesis:
 - Hand-tight and avoiding excessive torque
 - Prevent rotation of the implant during this operation
- Do not re-use screws from the dental laboratory for clinical use.
- Be sure to use the appropriate reference for each case.
- The minimum number of turns to ensure a good anchorage between five or six, in case of lower number of turns a longer screw shall be used (for more information contact: info@ipd2004.com)
- The tightening torque recommended for definitive prosthesis, if not shown on the product label is on the table below:



GENERAL AND PARTICULAR INSTRUCTIONS FOR USE

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Métrica	Torque
M2,5	30 N.cm
M2	20 N.cm
M1,8	20 N.cm
M1,6	20 N.cm
M1,4	15 N.cm
TORX	30N.cm
UNIGRIP	30N.cm
CUADRADO	30N.cm

Tabla 2, relación de métricas con torque de apriete recomendado

9. PSD. OVERDENTURE ABUTMENT

It is necessary to verify the compatibility with the model of implant to be used. We recommend a radiograph once screwed, at the height of the union with the implant and in the axis perpendicular to that joint, to check the good coupling of the assembly. It is advisable to position the patient so that, if the screw falls during the screwing / unscrewing maneuver, this fall occurs over an area where it can be recovered.

10. RETENTION INSERTS PSD

The PSD retainers must be handled with the corresponding tools distributed by IPD 2004 in order to avoid damage and deformation of the nylon inserts. It is necessary to replace the gums every 6 months or at the time when the patient feels little retention of his prosthesis for overdenture.

NON-STERILIZED PRODUCT: IPD 2004 products are not sterilized, but the possibility of sterilizing them is guaranteed

USEFUL INFORMATION ABOUT PRODUCTS MANUFACTURED BY IMPLANT PROTESIS DENTAL 2004 S.L

Please read with attention the instructions below to ensure a safe and efficient use of the products supplied by Implant Protesis Dental 2004 S.L.

The entire product range is designed so as to facilitate the work, both in the clinic and dental laboratory, while providing the best quality. Product features and compatibilities are expanded in the commercial catalog; if in doubt please get in touch with us (info@ipd2004.com).