



IFU
INSTRUCTIONS FOR USE

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GENERAL INSTRUCTIONS FOR USE

Indication for use

Implant Abutments and Screws are used for prosthetic restorations of dental implants or for assisting procedures in the dental laboratory.

Manufacturer

All the products that commercialize and distribute Implant Protesis Dental 2004 S.L. have been manufactured in the facilities of IPD2004.

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

Website: www.ipd2004.com. Tel: +34 93 278 84 91.



Storage and Handling

All products manufactured by Implant Protesis Dental 2004 S.L. 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 Protesis Dental 2004 S.L. products are delivered in a non-sterile state.

Compatibility Information

All IPD Abutments and Screws are available for a variety of connections. Implant system compatibility chart below.

IPD Series	Implant System	Platforms Diameters
AA	Nobel Biocare® Branemark System®	3,5 / 4,1 / 5,1
AC	Nobel Biocare® Replace Select	3,5 / 4,3 / 5,0
AD	Nobel Biocare® Nobel Active	3,0 / 3,5 / 4,3
BA	Biomet 3i® Osseotite®	3,4 / 4,1 / 5,0
BB	Biomet 3i® Certain®	3,4 / 4,1 / 5,0
CA	Klockner® SK2 – NK2	4,3
CB	Klockner® Essential Cone®	4,5
DA	Straumann® Tissue Level	4,8 / 6,0
DB	Straumann® Bone Level	3,3 / 4,1
EA	Astra® Osseospeed TX™	3,0 / 3,5-4,0 / 4,5-5,0
EB	Astra® Evolution®	3,6 / 4,2
FA	Zimmer® Screw vent®	3,5 / 4,5 / 5,7
IA	Dentsply® Friident® Xive®	3,4 / 3,8 / 4,5
IB	Dentsply® Ankylos®	C/X
JA	Camlog® Camlo® Implant System	3,3 / 3,8 / 4,3
LB	Biohorizons® Tapered Internal	3,0 / 3,5 / 4,5 / 5,7
MA	Swedden & Martina® Outlink®	3,3 / 4,1 / 5,0
MB	Swedden & Martina® Premium™ Kohno®	3,3 / 3,8 / 4,25 / 5,0
TA	MIS® Seven®	NP / SP / WP
TB	MIS® C1/V3®	Standard

Code Product	Type of product
IPD/___/(H/R)/___	Engaging or Non-Engaging Castable
IPD/___/A/___	Analog or digital analog
IPD/___/D/___	Healing Abutment
IPD/___/I/___	Interface Abutment
IPD/___/P/___	Cementing Abutment and Temporary
IPD/___/C/___	Impression coping
IPD/___/S/___	Scan Abutment
IPD/___/B/___	Co-Cr base w/o Castable
IPD/___/L/___	Overdenture Abutment PSD
IPD/___/T/___	Screws
IPD/___/M/___	Multi-unit Abutment

Contraindicaton

All materials used are biocompatible; however, some patients may present allergies or hypersensitivity to any of the materials and its components.

All IPD Abutments and Screws can only be combined with the corresponding compatible implant system. No abutments inappropriate in connection geometry should be used. Any post processing at the connection geometry to the implant may result in fitting inaccuracies prohibiting further use.

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.

Warning

Items supplied Implant Protesis 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 Protesis Dental 2004 S.L., is guaranteed only when trained professionals use them.

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

Sterilization

ALL PRODUCTS ARE SUPPLIED NON-STERILE. For sterilization, we recommend autoclaving the product at 121°C for 30 minutes, drying time 30 minutes (in accordance with standard UNE-EN ISO 17665-1:2007). Some devices are marked for "Single use only" because it is difficult or impossible to

clean and decontaminate a used device, reuse can lead to cross-infection. Furthermore, any attempt to reuse a device greatly increases the risk of mechanical failure caused by material fatigue. Any warranty claim resulting from the reuse of a single-use device will not be accepted.

Autoclave is the most commonly used method in clinics and dental laboratories. A physical agent, moist heat, which causes protein denaturation and coagulation, produces sterilization. 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, intermolecular hydrogen bridge bonds that can be broken and replaced by water at high temperatures stabilize the secondary and tertiary structures of proteins.
- Water steam has a much higher heat transfer coefficient than air. Wet materials, which conduct heat faster than dry materials, due to the energy released during condensation.



















→ Advantages

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

→ Disadvantages

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

LABELING SYMBOLS: ISO 15223-1:2016

ISO 15223 Symbology	Description	IPD Symbology	Description
	Manufacturing date		Recommended torque (Ncm) 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 (0051)		
	Product Reference		
	Non Sterile Product		
	Federal law restricts this device to sale by or on the order of a dental professional.		21 CFR 801.109(b)(1)

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 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).

SPECIFIC INSTRUCTIONS FOR USE

Eng / Non-Eng Castable – Material: POM

The castable abutment is for prosthetic restorations prepared by dental technicians in the dental laboratory. No waste. Observe the following precautions:

- Use a flash of wax that will create sufficient gap around the abutment to compensate for the greater dilatation coefficient between the castable material and its surroundings.
- Gentle torque to prevent deformation.
- Perform castings of a size and form that favours filling of the cavities and prevents the appearance of air bubbles.
- Use materials with high fluidity for castings in conflictive models.



Analog / Digital Analog- Material: Stainless Steel AISI 303

The analogs are for simulation of dental implant connection and position on a stone master model. A sealed and passive connection is needed. For use as a conventional analog must secure a sufficient fixing part anti-rotating and anti-stripping. Verify the compatibility of the connection, in type and size, between the analog and the prosthetic element prior to tightening. Do not reuse.



Screwdrivers – Material: Stainless steel ASTM F899

The Screwdriver should be used to fix the screws to the implant (clinic) or analogs (laboratory). If it's used intraorally, the screwdrivers should always be sterilized by means of autoclaving. The IPD screwdrivers are only connected to the handles with an RA shank. By use of exchangeable screwdriver, tips may be used for various implant Systems. The screwdriver tips should be used manually and should never be used with electric micromotors. Always check that the tip is fixed on the handle once it has been attached. The screwdrivers deteriorate over time, so they must be replaced regularly to avoid damaging the screw head.



Healing Abutment – Material: Titanium grade 5 Ti6Al4V

The healing abutment is used on the patient as an auxiliary transmucosal abutment. It is placed on the implant fixture before prosthetic restoration to facilitate the formation of a soft tissue. The height of this element will be selected to ensure its correct function and prevents the stress transmission. Before placing ensure that implant platform stays free from any tissue residues. Use gentle manual torque when installing.



Interface Abutment - Material: Titanium grade 5 Ti6Al4V

The interface is used for prosthetic restorations prepared by dental technicians in a dental laboratory. 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. To improve cement adhesion we recommend that it be thoroughly cleaned and degreased before cementation. The cementing zone of the ceramic surface of the mesostructure should be sandblasted and cleaned/degreased.



The TiN coating favors a better aesthetic finish.

Custom interface is adjustable in height. Consult the catalog for more information:

<https://ipd2004.com/products-guide>

This product is enabled to be used with IPD CAD-CAM libraries. You can request them by clicking the following link: <https://ipd2004.com/cad-cam>

Cementing / Temporary Abut - Material: Titanium grade 5 Ti6Al4V

Straight and angled abutments form the core of prosthetic crowns and bridges or are used for their support. Make sure that the engaging parts of the abutment are correctly aligned with the implant retention parts and that they are in the correct place and position for all secondary parts. 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 abutment-implant is recommended in order to ensure the correct adjustment. Remove excess cement from edge of the crown to avoid peri-implantitis, which can lead to implant loss.



Impression coping – Material: Titanium grade 5 Ti6Al4V

Are provided for use in open tray, for the transfer of implant position from the intraoral situation to the model in dental laboratory. 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. After tightening, place the impression tray to ensure full access to transfer screws from outside. Before impression, taking the transfers can be ferulized with acrylic resin placed over dental floss between consecutive implants. After hardening release all screws and take out the impression tray.



Scan Abutment – Material: PEEK / Titanium grade 5 Ti6Al4V

Indicated for obtaining geometric data from the master model using a desktop laboratory 3D scanner or for optical impressions using intraoral 3D scanner. 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.

For greater scanning precision, we recommend locating the flat surface of the scan abutment in palatine/lingual orientation. Fasten the abutment using the corresponding screw by hand or with maximum 10 Ncm. Scan abutment is a precision tool and over-tightening may change its geometry causing errors in scanning process and discrepancy in accuracy.

Two different heights are available, 10 mm and 15 mm depending on the gum height.

If this product for an intraoral scan, it is important to sterilize first.

This product allows to work with CAD-CAM libraries, direct implant and indirect implant via interface. You can request them by clicking the following link: <https://ipd2004.com/cad-cam>



Co-Cr base w/o Castable – Material: POM C / Co – Cr Alloy

The Co-Cr abutment is an implant abutment that consists of a Co-Cr alloy base and a fully burnout castable. Available with straight castable, and angled 15 and 25 degrees. The laboratory processing of the Co-Cr base abutment utilizes the cast-on technique. You need to check compatibility with the implant model you are bonding. Damaging the implant connection area should be avoided when carving or machining. The ceramic used with this alloy should have a expansion coefficient of 14.1×10^{-6} at 500°C or approximate.



Temp. range	Expansion Coefficient
20 to 300°C	13.5 x 10 ⁻⁶ cm/cm/°C
20 to 400°C	13.8 x 10 ⁻⁶ cm/cm/°C
20 to 500°C	14.1 x 10 ⁻⁶ cm/cm/°C
20 to 600°C	14.5 x 10 ⁻⁶ cm/cm/°C
20 to 700°C	15.1 x 10 ⁻⁶ cm/cm/°C
20 to 800°C	15.5 x 10 ⁻⁶ cm/cm/°C
20 to 900°C	15.9 x 10 ⁻⁶ cm/cm/°C
20 to 1000°C	16.4 x 10 ⁻⁶ cm/cm/°C
20 to 1120°C	16.5 x 10 ⁻⁶ cm/cm/°C

if the temperature or expansion coefficient are to high or low, the ceramic could break due to bad the fitting.

Precaution:

- Do not drip. Remove the coating carefully so as not to damage the morphology of the piece. Use fiber sticks or glass beads at low pressure.
- Keep the preheating oven on longer than usual.
- Revise the metal with the usual tools.
- If possible, re weld the union of the two metals (the machined base and the casted area) with a laser dot welder.
- Use ceramics with expansion coefficient of never less than 13.8×10^{-6} cm / cm / °C.

The bases of Co-Cr can only be used through the IPD CAD-CAM libraries. You can request them by clicking the following link:

<https://ipd2004.com/cad-cam>.

Co-Cr bases are enabled to be used with our libraries, easing the Scanning with a Scan Abutment (PEEK) that fits perfectly on the base. We dispose of the libraries for straight jobs and angled jobs for those that require a correction of the trans-occlusal channel.

We provide two adjustment options:

- The "Cast" tolerance for casting.
- "Sint" for welding.



PSD. Overdenture Abutment – Material: Titanium grade 5 Ti6Al4V

Indicated for removable dentures. It is necessary to verify the compatibility with the model of implant to be used. An X-ray in the perpendicular axis to the union interface-implant is recommended in order to ensure the correct adjustment. Available in different heights according to the height of the gum.

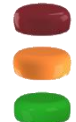
The retention insert part can be mounted in dental clinic as well as in dental laboratory with self-curing resin using standard techniques.

The TiN coating favours a better aesthetic finish and improves implant retention.



PSD Retention Inserts – Material: Nylon

IPD retention inserts is a part of the anchoring system for full or partial overdentures on implants. The retention inserts for PSD must be handled with the corresponding tools distributed by IPD 2004 in order to avoid damages and deformations in nylon retentions. It is necessary to replace the gums every 6 months or at the moment when the patient feels little retention of his overdenture prosthesis.



	Blue	Grey	Natural	Red	Orange	Green
Retention	Light	Medium	High	Light	Medium	High
Divergence	up to 20°	up to 20°	up to 20°	up to 40°	up to 40°	up to 40°

Screw – Material: Titanium grade 5 Ti6Al4V

The screw is for fixing prosthetic restorations and auxiliary abutments over implant or analog. 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.
- New screws should be used for the first fitting a prosthesis as for future revisions.

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
- Check compatibility of the screw with the implant model to which it will be connected.
- Position the patient to avoid aspiration in case the screw falls during screwing/unscrewing.

The tightening torque recommended for definitive prosthesis is shown on the product label is. For more information about the characteristics of the screws, you can consult on our website:

<https://ipd2004.com/technical-information>

Some screw models are available with TiN coating to provide a low friction surface, which improves the preload of the screw and provide better hold.



Multi-unit® Abutment – Material: Titanium grade 5 Ti6Al4V

Multi-unit is a transepithelial abutment. A pre-manufactured dental implant abutment directly connected to the dental implant intended for use as an aid in prosthetic rehabilitation for multiple fixed-removable prosthesis or screw-retained. An X-ray in the perpendicular axis to the union abutment-implant is recommended in order to ensure the correct adjustment.

Take an impression in a standard procedure and provisionalize the patient. If temporary prosthesis is not necessary, place healing caps.

Straight Multi-unit®: Torque recommended 30 Ncm.

Angled Multi-unit® and prosthesis: Torque 15 Ncm.

