I.INSTRUCTIONS FOR GENERAL USE

1 – PRESENTATION AND STORAGE

Trade name: IBODONTIT

Trademark: IBO

IBODONTIT, S.L. supplies its device clean, disinfected, perfectly packaged and shrink-wrapped. The device is NOT sterile upon delivery and therefore should be sterilised prior to being used in the mouth.

The device should be stored in its original packaging in a clean, dry place at room temperature, away from sunlight.

2 – INDICATIONS AND EXPECTED CLINICAL BENEFIT

The use of products supplied by IBODONTIT, S.L. allows the oral restoration in patients completely or partially edentulous. This will grant a proper mastication of the food ingested.

It is indicated for use in patients whose dentofacial development is complete.

3 – WARNINGS AND CONTRAINDICATIONS

The devices supplied by IBODONTIT, S.L. are intended for completely or partially edentulous patients, who require an oral restoration. These restorations can be unitary, multiple or overdentures.

Under no circumstances should the device be removed from the packaging provided unless the device is to be used. Prior to removing the device from its packaging, check that the device has not been damaged and that it matches the description given on the label. Check the integrity of the device prior to use.

Packaging defects can affect decontamination and disinfection properties. If packaging is damaged, the device should be returned and a replacement device should be requested.

Devices supplied by IBODONTIT, S.L. should only be used by professionals who have dental/prosthetic experience and knowledge regarding the handling/use of such devices. The person performing the treatment is solely responsible for handling/use of the device. IBODONTIT, S.L. only guarantees the safety and efficacy of its devices when these are used by properly trained professionals.

Carefully read device labels containing basic guidelines for device use.

IBODONTIT, S.L. supplies devices for clinical and laboratory use. The professional performing the treatment is responsible for using each device as specified in the instructions for use and for deciding which devices to use based on each patient's medical condition. Use of these devices is contraindicated if the patient is not fit for dental implant placement surgery.

The person using the device is responsible for ensuring the device is traceable at all times. Make a note in the patient's medical records of the device used, its name and lot number and inform IBODONTIT, S.L. of any anomaly.

IBODONTIT, S.L. recommends using all its devices ONLY ONCE. Reusing devices can lead to impaired features due to wear and tear, which may affect the patient's health and lead to tissue infection. IBODONTIT,

S.L. does not accept any responsibility for any attempt to reuse devices labelled as single-use devices.

The shelf-life of reusable devices depends largely on the way they are handled during use and between uses. Inspections and functional tests are recommended prior to each use. Any device showing signs of corrosion or rust should be discarded.

All IBODONTIT, S.L. devices are not sterile upon delivery and therefore should be sterilised prior to being used in the mouth as indicated in point 4.

Dental personnel should always wear appropriate protective clothing for their own safety.

Allergies: the materials used are biocompatible. However, some people may be allergic to them or to any of the device's components.

IBODONTIT, S.L. recommends using Ø3.5 mm or smaller implant abutments for anterior implants only, excluding any other area of the oral cavity.

Temporary PEEK abutments should not be left in the mouth for longer than 180 days.

PREGNANCY/ LACTATION:

No data is available on the use of the dental abutments provided by IBODONTIT SL during pregnancy or lactation. For safety reasons, pregnant or nursing women should not be treated with IBODONTIT SL dental abutments.

CHILDREN:

There is no research about the efficacy and safety of IBODONTIT S.L dental abutments in children before skeletal maturity. For safety reasons, children should not be treated with IBODONTIT S.L dental abutments.

In the event of any serious incident involving any of the medical devices covered by these instructions, notify the manufacturer and the competent authority immediately.

4 – PRECAUTIONARY MEASURES

The following precautionary measures should be taken before or during treatment:

– Make sure that all items, components, accessories and instruments are complete, ready for use and available in sufficient quantities before each surgery;

– Ensure that dental personnel is wearing appropriate protective clothing for their own safety;

– Position the patient in such a way to minimise the risk of aspiration. Secure all items used in the patient's mouth to prevent aspiration and swallowing.

– Despite all precautionary measures adopted during the manufacturing and conditioning processes, there is a residual risk related to malpractice or individual patient conditions. Please, ensure a proper follow-up of the instructions for use and assess the suitability of each patient before the intervention to minimise these risks.

5 – SIDE EFFECTS AND CONTRAINDICATIONS

No side effects have been described directly linked to the use of products supplied by IBODONTIT, S.L.

Use of these products in patients that do not present optimal conditions for the surgical placement of a dental implant is contraindicated.

It is contraindicated the use of these products in patients with a known allergy or hypersensitivity to any of the components used on the manufacturing of abutments and accessories provided by IBODONTIT, S.L.

6 – STERILISATION AND CLEANING

Sterilise all devices in accordance with UNE-EN ISO 17665-1 prior to being used in the mouth. This standard recommends using a steam steriliser for fifteen minutes at 121ºC / four minutes at 134ºC, with the device sealed in a suitable sterilisation pouch since the packaging in which the device is supplied is not suitable for sterilisation. Drying time: 20 minutes.

For the USA: devices should be sterilised in a pre-vacuum steam steriliser at 132ºC for 4 minutes. Minimum drying time: 30 minutes. Both the steam sterilisers and any accessories used should be authorised by the FDA in accordance with AAMI ST79.

The professional should sterilise all surgical instruments prior to use and should prevent the device from coming into contact with unsterile objects in order to minimise the risk of contamination.

Reusable devices should be cleaned and disinfected as soon as possible after each use. Disassemble all components if appropriate. Rinse with cold tap water to remove gross contamination. Bathe in an enzymatic detergent solution (i.e. ENDOZIME®, Ruhof Corporation 6.0-7.5 pH) prepared as per manufacturer instructions for 5 minutes. Scrub thoroughly with a soft brush and/or pipe cleaner; especially very narrow lumens should be flushed with enzymatic detergent solution using a syringe. Rinse with cold tap water for a minimum of one minute. Bathe in a detergent solution (i.e. LIQUI-NOX®, Alconox, Inc. 8.5 pH) prepared as per manufacturer directions for 5 minutes. Scrub thoroughly with a soft brush and/or pipe cleaner. Rinse thoroughly with deionized/reverse osmosis water. Apply ultrasonic bath for a minimum of 10 minutes in an enzymatic detergent solution. Rinse thoroughly with deionized/reverse osmosis water. Dry with a clean, soft, absorbent, disposable cloth. Visually inspect for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary re-clean until it is visibly clean.

After this, the devices should be then sterilised again according to these instructions.

7 – SAFE PRODUCT ELIMINATION

Once the shelf life of the devices is over, IBODONTIT, S.L. products have to be disposed according to standards approved by the local competent authority, considering environmental requirements and taking into account different levels of contamination. Special attention should be given to physical and infectious hazards (possible contamination with potentially infectious substances human originated).

8- ADDITIONAL INFORMATION

For more information, please check the General Instructions for Use of dental abutments and *Summary of Safety and Clinical Performance (SSCP)* at: *www.ibodontit.com/ifus*

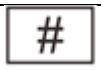
Patient information:

• The patient must follow all the instructions specified by the professional in the preparation before and after implantation.

• To know the expected clinical benefit, warnings, precautions, side effects and contraindications, carefully read the general instructions for use available at: *www.ibodontit.com/ifus.*

9 – INTERNATIONALLY RECOGNISED GRAPHICAL SYMBOLS

According to ISO 15223-1:2021:

SYMBOL	DESCRIPTION
	Manufacturer
	Date of manufacture
	Catalogue number
	Batch number
	Use-by date
	Do not reuse
	Non-sterile product
	Consult instructions for use
	Do not use if package is damaged
	Only to be used by dental professionals or upon prescription
	CE marking for Class I Device
	CE marking for Class II Device. It bears the number of the Notified Body authorising its marketing
	Unique Device Identification
	Medical Device
	Contains hazardous substances
	Keep away from sunlight
	Model Number

II. SPECIFIC INSTRUCTIONS

10 – SCREWS CE 0051

Intended purpose: Screws are meant to be used to attach any prosthetic element, such as cores, abutments or castable posts, to the implant.

Warnings/Precautions: It is essential to check that the device is compatible with the implant to which it is to be attached.

To obtain good results, it is necessary to:

- Use the right size driver to tighten/loosen the screw. If you are unsure, check that the next size driver does not fit the screw head.

- Use at least the minimum number of turns required to tighten the screw, which is 5 or 6. If less turns are required, a longer screw should be used. The recommended torque for permanent prostheses, unless otherwise specified on the device label, is:

METRIC SIZE (mm)	TIGHTENING TORQUE (N·cm)
M1.4	15
M1.6	20
M1.8	20
M2	30
M2.5	30

- Confirm full osseointegration prior to applying the recommended torque. If immediate loading of an implant is required after its placement, attach components by hand as carefully as possible.

- Align all screws placed in the mouth with the implant shaft.

Screws are single use only, even in the laboratory, due to the possibility of wear during use. Under no circumstances should screws previously used in the laboratory be used in clinical settings.

Do not use screws without their original packaging for the final placement of prostheses.

Material: Made of Grade 5 titanium (DIN TiAL6V4-ELI) alloy in compliance with AISI F136 and ISO 5832-3.

11 – STRAIGHT AND ANGLED ABUTMENTS, BALL ABUTMENTS, TEMPORARY ABUTMENTS CE 0051

Intended purpose: These are used to attach prosthetic components to implants. They support prosthetic structures cemented on them. The Ball-Attach system is used for removable dentures (which can be mounted and unmounted by the patient itself). Abutments can be used in combination with cemented crowns and bridges to restore dental function and aesthetics. They should be used once the healing abutment has formed the mucosal tunnel and has been removed.

Warnings/Precautions: Abutments can be anatomically adapted. Appropriate drill bits that are in perfect condition should be used to adapt abutments, applying reduced pressure.

It is essential to check that the device is compatible with the implant to which it is to be attached.

We recommend taking an X-ray once the abutment has been screwed in place, at the height of the abutment-implant junction and perpendicular to this junction, in order to ensure that the devices are coupled correctly.

Any abutments used as part of temporary prostheses can be used for a maximum of 6 months.

Material: Made of Grade 5 titanium (DIN TiAL6V4-ELI) alloy in compliance with AISI F136 and ISO 5832-3 or PEEK. The surface of titanium abutments can be anodised.

12 – CoCr-BASED CASTABLE ABUTMENTS CE 0051

Intended purpose: These abutments are used to manufacture screwed prostheses, with the particularity of a high-quality tight fitting on the implant. Castable abutments/copings are made of a castable alloy base and a plastic coping that burns out without leaving residues. The plastic coping can be cut to size. These units are modelled using the standard prosthetic procedure.

Warnings/Precautions: It is essential to check that the device is compatible with the implant to which it is to be attached.

The implant-abutment junction geometry and contact platform should be completely free of plastic, wax and grease to prevent potential overcasting in this area.

The porcelain used with this alloy must have a coefficient of thermal expansion of approximately 14.1 x 10-6 at 500ºC.

The casting temperature of the alloy used in the metal-ceramic device should be clearly below 1400°C (solidus of the castable abutment/coping) to avoid fusion. The corresponding instructions for the device to be cast should be taken into account.

To avoid stress on the cast object, it is necessary to allow the flask to cool to room temperature.

CAUTION: Material classified by ECHA as CMR 1B hazardous substance (possible carcinogenic and toxic for reproduction).

Material: These abutments are made of a cobalt chromium in compliance with ISO 5832-12 and the castable coping is made from polyacetal copolymer (POM-C) in compliance with FDA standards and EEC 90/128.

13 – COVER SCREWS CE 0051

Intended purpose: Cover screws are used to cover the implant during submerged healing.

Warnings/Precautions: Once the implant has reached its final vertical and rotational position, place the cover screw on the screwdriver and screw into the implant. Gently tighten by hand.

Check that the product is compatible with the implant to which it is to be attached.

Material: Made of Grade 5 titanium (DIN TiAL6V4-ELI) alloy in compliance with AISI F136 and ISO 5832-3.

14 – HEALING CAPS CE 0051

Intended purpose: Healing caps are used to shape and contour the surrounding gum tissue until the implant has healed. This helps keep a space open to connect the future prosthesis once osseointegration is complete.

Warnings/Precautions: Screw the healing cap into the implant. Gently tighten by hand. Select the healing cap based on its height, which must match the thickness of the gum, and its diameter, which must match the requirements of the prosthesis.

Check that the product is compatible with the implant to which it is to be attached.

This device can be used for a maximum of 6 months.

Material: Made of Grade 5 titanium (DIN TiAL6V4-ELI) alloy in compliance with AISI F136 and ISO 5832-3 and polyacetal copolymer (POM-C) in compliance with FDA standards and EEC 90/128.

15 – INTERFACES (Ti-BASES) CE 0051

Intended purpose: Interfaces are used to support provisional prostheses cemented or screwed tot the implant. It can also be used as a small abutment.

The manufacture of prostheses with cemented titanium bases results in high-quality, perfectly fitting prostheses with low material and production costs.

Warnings/Precautions: Check that the device is compatible with the implant to which it is to be attached. IBODONTIT, S.L. supplies non-engaging interfaces (suitable for bridges, bars and multiple-tooth structures) and engaging interfaces (suitable for single-tooth structures).

Material: Made of Grade 5 titanium (DIN TiAL6V4-ELI) alloy in compliance with AISI F136 and ISO 5832-3, with an anodised surface.

Do not use narrow platform interfaces for posterior restorations (molars and premolars).

16 – LOCK-ATTACH ABUTMENTS CE 0051

Intended purpose: These are used to attach overdentures or partial dentures to endosseous implants.

Warnings/Precautions: LOCK-ATTACH abutments are screwed directly onto the implant and have a locking mechanism on the front for various attachment systems. Overdentures or partial dentures are attached to the LOCK-ATTACH abutments using the attachment systems (anchors) built into the dentures.

Any type of adaptation to the implant-abutment junction geometry impairs their fit, making them unfit for use. Abutment-denture attachment system junction areas should also not be adapted or modified since these are vital for ensuring stability and a good fit.

Check that the abutment is compatible with the implant model to which it is to be attached.

It is also important not to damage the implant-abutment junction area when fitting or machining.

We recommend taking an X-ray once the abutment has been screwed in place, at the height of the abutment-implant junction and perpendicular to this junction, in order to ensure that the devices are coupled correctly.

Material: Made of Grade 5 titanium (DIN TiAL6V4-ELI) alloy in compliance with AISI F136 and ISO 5832-3, with a titanium nitride (TiN)-coated surface.

17 – TITANIUM HOUSINGS CE 0051

Intended purpose: These are placed on overdentures or permanent partial dentures to house the various retention inserts of the LOCK-ATTACH and BALL-ATTACH systems.

Warnings/Precautions: as described on the general instructions for use.

Material: Made from a Grade 5 titanium (DIN TiAL6V4-ELI) alloy in compliance with AISI F136 and ISO 5832-3.

18 – RETENTION INSERTS CE 0051

Intended purpose: These form the connection between the metal housing (on removable dentures) and the corresponding ball or LOCK-ATTACH abutment.

Warnings/Precautions: The suitable retention insert should be selected according to the strength required.

Material: Made of polyamide 6.6 or nitrile butadiene rubber (NBR)-70.

19 – ANALOGUES OR IMPLANT REPLICAS CE

Intended purpose: This is the machined component that is used in the laboratory to replicate implants and their position in the patient's mouth when producing the prosthesis.

Warnings/Precautions: Check that the type and size of the analogue is suitable for the prosthetic element prior to screwing it into the model.

Material: All of our implant replicas are made of stainless steel in compliance with EN 10088-3.

20 – CASTABLE ABUTMENTS CE

Intended purpose: This is the castable plastic component that acts as the initial base for waxing the shape of the final crown core structure.

Warnings/Precautions: It should be positioned on the coronal part of the implant. The final structure will then be cast in the corresponding metal.

This abutment is available in non-engaging (for bridges or restorations) and engaging format (for single teeth).

A wax coating should be used around the abutment to offset the higher coefficient of thermal expansion of the castable material in comparison with the surrounding materials.

Gently screw in the abutment to prevent deformation.

Check that the product is compatible with the implant to which it is to be attached.

Material: All of our castable abutments are made from polyacetal copolymer (POM-C) in compliance with FDA standards and EEC 90/128.

21 – IMPRESSION COPING AND SCREW

Intended purpose: Impression copings are used to transfer the exact position of implants onto the model when using implant impression techniques.

Warnings/Precautions: It is essential to check that the device is compatible with the implant to which it is to be attached.

When using an open tray technique:

Remove the gingiva former. Clean the connection of the implant with air/water spray and dry. Select the impression coping, place in one of the possible indexed positions, make sure it is properly seated and tighten the impression coping screw by hand and then using the manual screwdriver. Take an impression using an open tray. Once set, loosen the transfer screw and remove. Then remove the impression with the impression coping.

When using a closed tray technique:

Remove the gingiva former. Clean and dry the connection of the implant with air/water spray. Place the closed tray impression coping in one of the possible indexed positions, make sure it is properly seated and tighten using the manual screwdriver. Then place the guide bushing on the impression coping until it reaches its final position. Take an impression using soft silicone, hydrocolloid or polyether. Once set, remove the impression. Leave the guide bushing in the impression. Mount an impression coping on a laboratory implant and then reinsert it into the impression. Make sure the impression coping stays in its final position inside the guide bushing. Make sure no impression material is trapped between the two components.

Material: Made of Grade 5 titanium (DIN TiAL6V4-ELI) alloy in compliance with AISI F136 and ISO 5832-3 or of stainless steel in compliance with EN 10088-3.

22 – MANUAL SCREWDRIVERS, DRILL EXTENDERS AND RATCHETS

IBODONTIT, S.L. supplies screwdrivers, drill extenders and ratchets. These are classified as class I medical devices.

Manual Screwdrivers CE:

Intended purpose: used to tighten caps, transmucosal abutments, abutment screws, intermediate abutments and prosthetic screws.

Warnings/Precautions: Manual Screwdrivers have an accessory to connect them to the screwdriver or manual torque wrench. Screwdrivers have an integral handle to hold and twist the screwdriver by hand.

Make sure the screwdriver is securely engaged in the screwdriver handle before placing it in the patient's mouth.

Insert the screwdriver in the hole on the handle and then gently press and twist until it is fully engaged. Make sure the end of the bit has engaged properly before exerting any force on the surface of the device to be screwed in.

Check that the screwdriver is compatible with the surface on which it is to be used.

Drill extenders CE

Intended purpose: These are intermediary elements used between the implant connection platform and the implant driver.

Warnings/Precautions: Based on the implant system used, implants are mounted in standard carriers or mounts.

Ratchets CE

Intended purpose: Ratchets are used to secure dental implants and screws during implant surgeries. A torque wrench can be used to apply a set torque.

Warnings/Precautions: as described on the general instructions for use.

Material: All of these surgical instruments are reusable and made of stainless steel in compliance with EN 10088-3.

23 – PROTECTIVE DISK CE

Intended purpose: The protective disk is briefly used to position the retention insert housing on the LOCK-ATTACH abutment. It is placed on the abutment to stop fluids from the patient's mouth from entering the titanium housing.

Warnings/Precautions: as described on the general instructions for use.

Material: Made of silicone in compliance with ISO 1629.

24 – SCAN BODY CE

Intended purpose: The scan body is used to record the exact position of the implant or abutment on the model (extraoral) or in the mouth (intraoral) in order to transfer that position correctly to a 3D model using a scanning process.

Warnings/Precautions: When using intraoral scan bodies, these should always be positioned with the patient's gums closed.

Abutments with an incompatible implant-abutment junction geometry should not be used. Any type of adaptation to the implant-abutment junction geometry impairs their fit, making them unfit for use. The shape of the scan body should also not be adapted or modified since this is vital for ensuring precise scanning results.
Remember when positioning the scan body that the outer longitudinal slice corresponds to the opposite side of the screw channel on the future prosthesis.

Material: Intraoral scan bodies are made of Grade 5 titanium (DIN TiAL6V4-ELI) alloy in compliance with AISI F136 and ISO 5832-3, with a zirconium nitride (ZrN) coating. Extraoral scan bodies are made of PEEK.

25 - PRE-MILLED BLANKS CE 0051

Intended purpose: Pre-milled blanks allow the production of one-piece customised metal abutments with a pre-machined connection. They are placed on dental implants to provide support to prosthodontic reconstructions, such as crowns or bridges, and are anatomically adjusted, ensuring that the implant-abutment junction is not altered.

Warnings/Precautions: Any alteration to the implant-abutment junction may affect its fit with the implant. During the finishing stage, the junction should therefore be protected from milling, polishing and sand-blasting processes.

Blanks are not sterile upon delivery and are for single use only. Prior to being placed in the patient's mouth,

the restoration should be cleaned, disinfected and sterilised. Clean the abutment under running water, brushing both sides with an appropriate brush. Once clean, disinfect using an automatic cleaning and disinfection device according to the manufacturer's instructions.

In order to design the prosthetic restoration, use CAD software and appropriate digital libraries supplied by IBODONTIT, S.L. for each case. Designs should not have sharp edges as these could cause injury to the patient's gum tissue. Once designed, mill the restoration according to the mill manufacturer's specific instructions, which should include the best tools for each design. Finally, coat the resulting abutment with a suitable porcelain coating material and apply the treatment as instructed by the coating material manufacturer.

Abutments with an incompatible implant-abutment junction geometry should not be used. Pre-milled blanks are suitable for use with various milling systems with the respective abutment support. Contact your mill supplier for more information about appropriate abutment supports and CAD/CAM integration.

Material: Made of Grade 5 titanium (DIN TiAL6V4-ELI) alloy in compliance with AISI F136 and ISO 5832-3.

If you have any queries, please contact us at:

Ibodontit, S.L.
Calle Felipe Sanclemente 6, piso 2º B y C.
50001 Zaragoza – Spain
Tel. +34 976 90 50 77
@: ventas@ibodontit.com