PIC dental®
PRECISE IMPLANTS CAPTURE

CE

INSTRUCTIONS FOR USE
PIC transfer

A PIC transfer is a reusable, coded abutment to transfer the position of dental implants by three-dimensional optical measurement, to facilitate the design and selection of dental prothesis.
A PIC transfer is intended to be used intraorally in the patient's mouth, mounting directly on the implant or on trans-epithelial abutment.

A PIC transfer is manufactured with technical polymer, a biocompatible material suitable for medical use.

PIC transfers are available for different platforms and sizes of implants. The individual product label and abutment marking indicate the type and size of the implant for which it is compatible.

PIC transfers are intended to be used together with other devices that are part of the three-dimensional optical measurement system:

- The PIC camera and the PIC suite software to locate the exact position of the PIC transfers.
- The third-party CAD/CAM software for the prosthetic design.
- Screws provided by PIC dental and/or compatible with the PIC transfer reference.
- Corresponding third party TORX screwdriver (E.g. Straumann original screwdriver) used to connect the screw to the rest of the elements.

For specific product descriptions, please refer to the individual product labels.

PURPOSE OF USE
A PIC transfer is a coded abutment to transfer the position of dental implants by three-dimensional optical measurement, to facilitate the design and selection of dental prothesis.

INTENDED POPULATION
A PIC transfer is intended to be used in the patient's mouth, mounting directly on the implant or on trans-epithelial abutment.

CONTRAINDICATIONS AND WARNINGS

Warnings related to the product
- Each PIC transfer reference must be used with the original implant or abutment for which it was designed.
- Allergies to materials may occur but are rare.
- Do not try to disassemble or deform a PIC transfer.

Warnings related to the use
- Before using the product, it must be sterilized and disinfected, as indicated in point 6 of these instructions for use.
- The PIC transfer must be used with an original digital library installed in the PIC suite software.
- Before use, you should ensure that the fit is correct, the PIC transfer connection and the implant platform, or abutment platform, is clean and free of debris, as well as bone or gingival tissue.
- You should check the stability of the implant before placing a PIC transfer. If abutment is used, you must ensure the proper seating by applying the manufacturer's recommended maximum torque.
- Do not use a PIC transfer that has been damaged or modified in any way. Using a modified PIC transfer may result in an erroneous scan.

Warnings related to the handling
- As the PIC transfer is a small element, it should be handled with care to prevent the patient from swallowing or inhaling it.
- Screw placement must be done manually (without electric screwdrivers), using the corresponding screwdriver.
- The maximum amount of torque is 10Ncm. Exceeding the torque limit can damage the PIC transfers.
- PIC transfers should only be used and handled by a professional odontologist with appropriate training (PIC pro training).

Warnings related to the maintenance and disposal
- After each use, the product must be sterilized and disinfected, as indicated in point 6 of these instructions for use.
- PIC transfers should be stored out of direct sunlight.
- PIC transfers must be disposed of as biowaste.

INSTRUCTIONS FOR USE

For correct use of PIC transfers, the following instructions must be followed in strict order:

Requirements and indications prior to a PIC system capture

1. It is a prerequisite to clean and disinfect the PIC transfer product according to the procedure described in section 6 of these instructions for use.
2. Remove the cover screw, healing cap or similar from the implant or abutment on which the PIC transfer product is intended to be placed.
3. Place the PIC transfer product over the implant/abutment in the patient's mouth.
4. Lightly tighten the screw using the corresponding screwdriver (maximum 10Ncm).

PIC system capture

1. Perform a PIC system capture following the instructions of the PIC system and PIC suite software to obtain measurements of the implant positions.
2. After scanning, remove the PIC transfers using the corresponding screwdriver.
3. After removing the PIC transfers, screw the scan markers on the implant or abutment, to record the gingival data using an intraoral scanner.

REPROCESSING
PIC transfers have been validated to maintain specifications for 200 uses, including their corresponding reprocessing cycles. The validation of the reprocessing cycle has been carried out according to the means and techniques widely extended among dental clinics.

There are 3 available methods approved and validated by the manufacturer according to the reference standard: "EN ISO 17664-1:2021. Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices."

To maintain the specifications during these 200 uses, the instructions provided below by the manufacturer must be followed:

Clean the instruments as soon as possible after using them in the appropriate location. Prevent blood or dirt from drying on the instruments. If it's necessary to delay cleaning and to avoid dirt from drying, place sets of instruments in a sealed container with cold water or an appropriate solution of detergent. Clean all instruments, even if they haven't been used or have been accidentally in contact with blood or saline solution.

1. PRELIMINARY CLEANING

- Ensure the cleaning process exposes all PIC transfer parts as per their geometry
- Personnel in charge of cleaning should use appropriate protective equipment, such as gowns, face masks and gloves.
- Remove the screws, leaving the PIC transfer screw channel free for cleaning.
- Contact areas, such as threads, cavities, and blind holes, should be cleaned carefully to remove all visible dirt.
- The PIC transfers must be rinsed with deionized water before beginning the cleaning and disinfection process.

2. ULTRASONIC BATH CLEANING

Cleaning materials:
- Water: Use cold deionized or reverse osmosis-purified water. Avoid temperatures above 60 °C to prevent protein coagulation and ensure effective removal from contaminated items.
- Medical grade detergent (neutral pH): Prepare according to the manufacturer's guidelines.

Preparation:
- Ensure the ultrasonic bath is clean and functional.

Fill the Ultrasonic Bath:
- Add the manufacturer-recommended quantity of detergent.

PIC dental®
PRECISE IMPLANTS CAPTURE

Instrument Placement:

- Fully submerge the PIC transfers in the ultrasonic bath without overcrowding.

Ultrasonic Cleaning Cycle:

- Start the ultrasonic cleaning cycle following the equipment's user manual.
- The ultrasonic bath will generate high-frequency sound waves that create microscopic bubbles. As these bubbles implode, they release energy that helps dislodge and remove contaminants from the instruments.

Rinsing:

- After the ultrasonic cleaning cycle, remove the PIC transfers from the bath.

Drying:

- If the ultrasonic bath equipment has a drying function, you can use it to dry the cleaned PIC transfers. Alternatively, you can use a separate drying process (e.g., using a fiber-free cloth or dry compressed air).

Visual Inspection:

- Inspect the devices for any remaining debris or contamination. If needed, repeat the cleaning process.

Follow Manufacturer's Instructions:

- Adhere strictly to the manufacturer's guidelines for the operation and maintenance of the ultrasonic bath equipment.

Consideration of Variables:

- Consider factors such as load size, detergent concentration, water temperature, and exposure time, as these can affect cleaning efficiency.

3. HIGH-LEVEL DISINFECTION AND STERILIZATION

Rely+On™ PeraSafe™ (CE approved)

PIC transfer reprocessing has been validated for high-level disinfection, within the European Union (CE mark, Regulation EU 2017/745), with Rely+On™ PeraSafe™ disinfectant. The instructions for use must be strictly followed.

After completing the PIC transfers reprocessing, store in an airtight container to prevent contamination before next use.

Revital-Ox® RESERT® (FDA approved)

PIC transfer reprocessing has been validated for high-level disinfection, within the USA (FDA, 21 CFR 800), with Revital-Ox® RESERT® disinfectant. The instructions for use must be strictly followed.

After completing the PIC transfers reprocessing, store in an airtight container to prevent contamination before next use.

Steam sterilization (Approved Autoclave Coltene SciCan Statim 6000B)

PIC transfer reprocessing has been validated for steam sterilization with the following sterilization schedule:

Preparation of sterilization bag:

Place the cleaned and rinsed PIC transfers into sterilization pouches or wraps suitable for autoclaving.

Loading the Autoclave:

Arrange the pouches in the autoclave chamber according to manufacturer's instructions, ensuring proper spacing for effective steam circulation.

Program Selection:

Choose the preset program for Universal Class B autoclave sterilization. **Set the parameters as follows**:

- Temperature: 134°C (273,20°F) / 3.5 min
- Pressure: 3.2 bar (320 kPas)
- Drying time: 5 minutes

Run the Sterilization Cycle:

Start the autoclave cycle.

Follow the recommended cycle times and phases:

- Suction Time: 5 minutes
- Admission Time: 5 minutes
- Sterilization Time: 3 minutes 30 seconds

Drying Phase:

Once the sterilization cycle is complete, the autoclave will proceed to the drying phase.

Allow the PIC transfers to dry for 5 minutes to minimize moisture.

Completion and Removal:

Once the drying phase ends, the sterilization process is complete.

Carefully remove the sterilized pouches from the autoclave.

Ensure strict adherence to the manufacturer's instructions for both the ultrasonic bath and the Class B autoclave. Regularly monitor and maintain the equipment to ensure effective reprocessing. Following these instructions will help ensure that the medical devices are thoroughly cleaned, disinfected, and sterilized for safe reuse.

CE

SYMBOLS

The meaning of the symbols included in the PIC transfer labeling is explained below:

	Symbol indicating the name and address of the PIC transfer manufacturer.
	Symbol indicating that PIC transfer is a medical device.
	Symbol indicating the need to read these instructions before using the PIC transfer product.
	Symbol indicating the unique identification code of PIC transfer.
	Symbol indicating the date of manufacture of the PIC transfer lot.
	Symbol indicating the reference of the PIC transfer model.
	Symbol indicating the lot number of PIC transfer.
	Symbol indicating the conformity of the product with the applicable requirements of EU Regulation 2017/745 on medical devices.

Please contact with the manufacturer for additional information.

IDITEC NORTH WEST S.L.
Phone: +34 919 491 235
C/ Camino de Valladolid 1
28250 Madrid – Spain www.picdental.com

For additional information on the use of PIC DENTAL products, or to report any adverse incidents, please contact your local distributor or visit www.picdental.com.

When an incident, adverse reaction or basic safety problem related to the product is suspected, please notify the Competent Health Authority (AEMPS) through the following link:
https://notificaps.aemps.es/enviotelematico/notificaps/notifica/inicio.do