CE

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CE Class I medical device according to European Directive 93/42/CEE

Warning: danger, you must read the accompanying instructions.

Read the precautions for use.

Do not reuse.

Non-sterile

Sterilise without packaging in an autoclave at the indicated temperature.

Expiration date

LOT Batch code

Do not use if the packaging is damaged

Keep in a dry place with a humidity rate between 30% and 70%

Keep away from light

Manufacturer

Date of manufacture

Description

The Digital Transfer is an accessory used for the design of dental prostheses in combination with an Axiom® REG or Axiom® PX implant, an intraoral camera and an implant range associated to the dental design application.
Materials used: thermoplastic polymer, titanium

Compatabilities

The Digital Transfer is compatible with the Axiom® REG and Axiom® PX implant ranges only.

Indications

The Digital Transfer is used only for establishing the precise positioning of an implant at a surgical site for modelling in a CAD dental design application.

Digital Transfer must only be used for a **single-unit implant restoration**.

Warnings and Precautions for use

The Digital Transfer and its associated screw must be used intraorally only. The screw delivered with the device is compatible with the Digital Transfer only. Any other use of this screw is prohibited.

The Digital Transfer must be sterile when used.

⚠ The Digital Transfer must be immobilised on the implant through a LIGHT MANUAL TIGHTENING with the INCHECV, INCHELV or INCHEXLV hexagonal wrench. Too much tightening will decrease digital precision and may deteriorate the Digital Transfer.

The Digital Transfer is a precision tool and must be used with care.

⚠ The Digital Transfer is designed to be used only once; do not reuse it or re-sterilise it.

Damage to the Digital Transfer may interfere with proper positioning of the implant and the passivity of restorations supported by an implant.

Cleaning – Sterilisation

General Information:

Only personnel who have been properly trained and are adequately protected in accordance with current legislation may clean, disinfect and sterilise the device. To avoid any risk of infection or injury, proper protection must be worn (mask, gloves and protective goggles). Protocols for cleaning, disinfection and sterilisation must be appropriate for infectious risk. The user or medical personnel must ensure that the protocol results in correct sterilisation. The protocol must enable eliminating any chemical and organic residues on the device (be especially careful to thoroughly rinse the products used).
To implement the protocol, current regulations must be strictly followed. See the recommendations found in "Best Practices in Hospital Pharmacy", in the guide to "Best Practices in Disinfection", in the guide to "Best Practices in Sterilisation" and in the "Guide to Proper Treatments for Reusable Medical Devices" of references FD S98-135 dated April 2005.

To avoid deteriorating or damaging parts, only cleaning and decontamination products that are compatible with the various combinations of materials must be used. Detergent or disinfectant solutions must have a neutral pH or be slightly alkaline.

Products:

To guarantee proper decontamination before sterilisation, detergent and disinfectant products must be chosen according to infectious risk and their area of application – standard microbial activity (bactericide, fungicide, virucide, etc.) – and their ability to clean. Use of detergent and disinfecting solutions must correspond to the cleaning technique used.

For each cleaning and disinfection product, the user must follow the manufacturer's instructions:
- Use the indicated concentrations, temperatures and exposure times.
- Renew the solutions as often as required and pay attention to the length of product life.
- Eliminate products used according to recommendations.
- Never mix products.

WARNING! Do not use substances that may set proteins (alcohol, aldehydes, etc.).

For more information, the user may refer to guide no. FD S98-135, the "Guide to Preventing Infections Related to Dental Surgery and Stomatology", dated July 2006, and to the positive list of dental disinfectants published in 2009 by the SFHH (French Society of Hospital Hygiene) and the ADF (French Dental Association).

Water used for pre-disinfection, cleaning, decontamination, rinsing and sterilisation must comply with current regulations. The user may consult the document entitled: FD S 98-135, §9-4. Water quality must be compatible with the sterility goal and with equipment used. It is important to pay attention to conductivi-

ty parameters, pH, hardness, ion and impurity concentrations and microbiological pollution.

The user must pay particular attention to removing dirt, residues and deposits from all parts of the tools (holes, slits, etc.) A visual check must be made before each sterilisation. The elimination of medical waste must comply with current legislation concerning medical waste.

Protocols:

1. Cleaning - Disinfection

Parts must be dismounted and cleaned separately.
Cleaning with a brush:
Carefully brush with a soft brush (nylon, for example).
Immerse completely in a detergent and disinfectant solution according to the manufacturer's recommendations.
Rinse with demineralised, reverse-osmosis water to avoid deposits.
Dry immediately with care on a soft, sterile, lint-free ground and finish with medical-quality compressed air.
Check the results and redo the cleaning operation if necessary.

2. Sterilisation

Parts must not be sterilised without previous cleaning, disinfection and drying.

Autoclave sterilisation:

Place each part separately in a sealed sterilisation bag compliant with the NF EN ISO 11607 standard and appropriate for the sterilisation method.
Run an autoclave steam cycle at 135°C (275°F) and 2.13 bars (30.88 psi) for a minimum of 20 minutes.
Indicate sterilisation and expiration dates on the bag, according to the sterility time limits set according to the type of packaging and storage conditions (one month maximum).
WARNING! Do not use any other method of sterilisation. Anthogyr recommends using Class B autoclaves.

Follow the autoclave manufacturer's recommendations and instructions for autoclave use and upkeep.
Leave enough room between bags inside the autoclave.
Comply with the conditions for keeping sterile parts, as recommended by the bag manufacturer.
See French circular DGS/5C/DHO/E2 no. 2001-138 dated March 14, 2001.

Digitisation protocol

- Manually screw the Digital Transfer device on the Axiom® REG or Axiom® PX implant using the hexagonal wrench and the screw supplied with the device.
- Digitise the site with the help of the intraoral camera.
- Remove the Digital Transfer device by loosening the screw.

Safety and responsibility

Correct use and manipulation of this product are the user's responsibility.

Anthogyr-Simeda shall not be held responsible for failure due to not following the protocol.

Anthogyr-Simeda thanks you for your trust and will be happy to furnish you any additional information.