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.

Do not re-sterilise.

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

Digital transfers are accessories used to design dental prostheses in combination with an Axiom® TL or Axiom® BL implant or an inLink® or Multi-Unit abutment, with an intra-oral scanner and an implant library associated with the dental design software. Each digital transfer is supplied with its own screw. A laser marking on each digital transfer identifies its implant platform compatibility.
Materials used: Radiopaque thermoplastic polymer, Titanium.

Compatabilities

Digital transfers are compatible with the range of Axiom® TL and Axiom® BL implants and with the Multi-Unit and inLink® abutments.

Indications

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

Digital transfers must be used in **single or multiple restorations**, **as indicated in the table below**.

Warnings and Precautions for use

Digital transfers and their screws are for intraoral use only. Digital transfers are supplied with their own screw. This screw is only compatible with the digital transfer contained in the same package. Any other use of this screw is prohibited.

Digital transfers must be used sterile.

Digital transfers must be secured on the implant with **light manual tightening** using a hexagonal wrench *(Items INCHECV, INCHELV or INCHEXLV)*. Excess tightening alters the position of the implant in the CAD dental design application and may damage the digital transfer.

Digital transfers are precision parts that must be handled with care.

Digital transfers are designed to be used only once; do not reuse them or re-sterilise them.

Damaged digital transfers can compromise the proper placement of the 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.

Digital transfers item	Indication	Implant platform compliance
152-27-DT	Single	Axiom® BL implant
156-01-DT	Single	N Ø4.0 Axiom® TL implant
156-02-DT	Single	R Ø4.8 Axiom® TL R Ø4.8 implant
156-01-DT-IL	Multiple	Axiom® TL implant / N Ø4.0 inLink® abutment
156-02-DT-IL	Multiple	Axiom® TL implant / R Ø4.8 inLink® abutment
151-03-DT-MU	Multiple	Ø4.8 Axiom® BL Multi-Unit abutment
151-04-DT-MUN	Multiple	Ø4.0 Axiom® BL Multi-Unit abutment

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 conductivity 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.

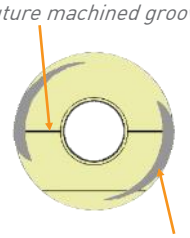
Follow the autoclave manufacturer's recommendations and instructions for autoclave use and upkeep.
Leave enough room between bags inside the autoclave.
Comply with the conditions for keeping sterile parts, as recommended by the bag manufacturer.
See French circular DGS/5C/DHO/E2 no. 2001-138 dated March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

Digitisation protocol

•Manually tighten the digital transfer(s) on the Axiom® BL or Axiom® TL implant (s) or on the Multi-Unit or inLink® abutment(s) using a hexagonal wrench and the supplied screw.
•Digitise the site using an intraoral camera.
•Remove the digital transfer(s) by unscrewing the screw(s).

For items 156-01-DT-IL and 156-02-DT-IL, please observe the following recommendations:

The laser marking on the top of the Digital Transfer determines the position in the prosthesis of the future machined groove.



Machined groove housing the retaining ring

To minimise the space taken by the prosthesis in the vestibular and lingual area, place the laser marking of the digital transfer in the prosthetic groove

Safety and responsibility

Correct use and handling of these products are solely the user's responsibility.

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

The quality of the digital marking is the practitioner's responsibility.

The design of the prosthesis will be based on the same digital impression, thereby determining the compliance and quality of the final prosthesis.

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