Photography Focus - Intraoral Photographic Mirrors

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REF **DB04-0160, DB04-0161, DB04-0161C, DB04-0162, DB04-0163, DB04-0164**

*Read these instructions for use carefully before each use and keep them easily accessible for the users or the relevant specialists.Please refer to the specific information on intended purpose, indication and contraindication.Carefully read these instructions for use. Improper use of the products may result in serious injury to the patient, the user or third parties *Notice to user that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.*

Product Description

The medical device Intraoral Photographic Mirrors are mirrors with chrome-plated surface. This feature allows a very sharp and clear image mirroring. No artifacts, double reflections are visible into both the mirrored image and the camera picture.

Intended Use and Indications

Intraoral Photographic Mirrors are intended to be used for dental diagnosis and diseases prevention. Should be used only by properly trained and qualified medical staff. The product is intended exclusively for the medical field described above and must therefore be used in a suitable medical environment. It is mandatory that the user and the relevant specialist staff become familiar with the product and this instruction for use before use it. Intraoral Photographic Mirrors are indicated to grab pictures of mouth anatomical site when is not possible or not easy to reach the target of the picture. It can be used on both adult patients and children patients according the chosen size or part number. The device is supplied not sterile and in a not sterile plastic bag. The device must be cleaned and sterilized before use according this instruction for use. Sterilization and Reprocessing of the device is validated according EN ISO 17644 International Standard.

Operating Conditions

To ensure safe operation of the aforementioned product, proper maintenance and care of the products are essential. In addition, a functional or visual check should be carried out before each application. The manufacturer assumes no liability for any consequential damage caused by improper use or handling of the product.

Instruction for use for Reprocessing and Sterilization

The medical device is shipped in **non-sterile condition** and must be processed and sterilized by the user in accordance with the instructions below before the first as well as before any further application.

Inspection and Preparation

Before use check the surface and edges for non uniformities and sharpness. Do not use the device if either the surface or the edges are damaged or sharped, they can injure the patient and/or operator. If your inspection of the new instrument confirms it is in perfect condition proceed with the cleaning and sterilization as provided in this document. Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used. Wherever possible avoid the use of abrasive agents. Follow hospital/facility approved Health & Safety procedures at all times. Wear protective clothes, gloves and eye wear as specified in your Health and Safety procedures.

Manual Cleaning

Manual cleaning is not recommended when an automated washer-disinfector is available. For a proper cleaning, it is suggested to dip the medical device in neutral enzymatic cleaning 0.5% solution for 5 minutes (GIOPLURIZIM 0.5%), then remove from the bath and carefully brushed with a soft sponge to remove all the visible dirt or residuals. Rinse under a volume of cold running tap water (10-15°C) corresponding to about 20 liters for 2 minutes, moving them slightly to allow water to reach the entire surface, to remove any detergent residues.

Manual Disinfection

Manual Disinfection is not recommended when an automated washer-disinfector is available. For a proper disinfection, it is suggested to brash with an absorbent cloth soaked with alcohol-based solution for 1 minutes (GIOALCOL), then dry with an absorbent cloth that leaves no residues.

Automated cleaning and disinfection

We recommend using a washer-disinfector meeting the requirements of ISO 15883 series. Automated cleaning and disinfection instruction:

- washing in cold water with the enzymatic detergent (GIODETER MATIC E)
- thermal disinfection at 93°C +/-2 °C for 10 minutes;
- neutralization in cold water with the use of an acid liquid neutralizer (ACIDGLASS P2) for 2 minutes;
- rinse with demineralized water for 2 minutes;
- rinse with hot demineralized water (75°C) for 1 minute;

At the end of the cycle, dry with an absorbent cloth that leaves no residues. The specific instructions by the manufacturer of the automatic cleaning/disinfection machine must be observed. After the cycle is finished, the instruments need to be inspected as per Inspection/Function Testing as following:

- check the surface and edges for non uniformities and sharpness. Do not use the device if either the surface or the edges are damaged or sharped, they can injure the patient and/or operator.

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Sterilization
Sterilization of the products using the fractionated pre vacuum process (according to EN ISO 17665-1), taking into account the respective national requirements. The products must be sterilized in suitable sterilization packaging. The sterilization is to be carried out using a fractionated pre vacuum method with the following parameters:

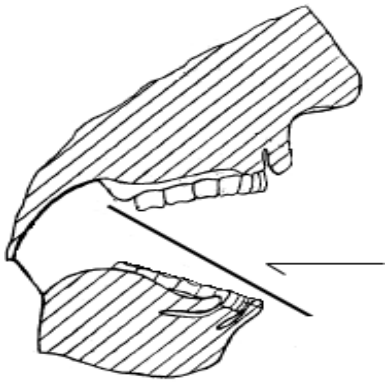
- temperature: 134°C ± 3°C
- time: 10 minutes
- pressure: 2 bar ± 1 bar

Storage
Following sterilization processing, packaged instruments may be stored in a clean area free of temperature and humidity extremes in accordance with your facility's policies.

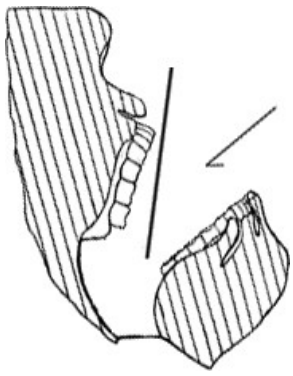
Additional Information
Other forms of cleaning and sterilization are available, but always follow the instructions for use as issued by the processing equipment manufacturer and always consult with them if in any doubt over the suitability of any process used. Any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences. All cleaning and sterilization processes require validation at the point of use. The instructions provided above have been validated as being capable of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed, using equipment, materials and personnel in the processing facility, achieve the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

Product life
If stored in the original packaging, the medical device is valid for 5 years from the date of manufacture. The service life of the products essentially depends on the careful handling during application and processing of the products by the user. However, the product is validated for 25 cycles of sterilization, but can be used until that the user does not recognize any evidence of damages or any other alteration of the product (ex. Removal of the chrome layer). In this case reject the product and change it with a new one.

How to use it
Just before the use, in order to prevent fogging, run the mirror under hot water for a few seconds. Use a soft towel or sterile gauze to remove droplets. The device is inserted manually into the patient's mouth, in positions that may vary depending on the investigation area or depending on the area you want to photograph. Carefully introduce the device into the patient mouth as shown below.



Maxillary Picture



Mandibular Picture

Disposal methods
After use, throw the device in the appropriate containers if it is no longer used.Do not disperse in the environment.

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Symbols used on labels

⚠	Warnings or Precautions		Manufacturer
REF	Catalogue number	NON STERILE	Not sterile Product
LOT	Batch number		Fragile
	Manufacturing date		Consult instruction for use
CE	Medical Device according to EU Regulation 2017/745		