

Mirrors for Dental Photography

Instructions for use

With the purchase of these mirrors for dental photography, you receive a high-quality product.

In order to minimise hazards for the patient and the user, please read the instructions for use carefully. The use, disinfection, cleaning and sterilisation of the mirrors may only be carried out by trained specialists.

Scope of validity:

The instructions for use are valid for the following mirrors for dental photography:

- Types A, B1, B2 & C, for occlusal photographs
- Type D, for lateral photographs
- Type S, mirror set
- Type O, for occlusal photographs without handle
- Type L, for lingual photographs without handle

Intended use:

The mirrors are intended for photographic documentation during dental examinations.

The photographs are used for treatment planning, reassessment during treatment and final and late findings.

The mirrors must not be used contrary to their intended purpose, as this may result in damage or breakage.

Safe handling and provision:

- Use and preparation by trained personnel only.
- Read, follow and keep the instructions for use
- Use product only as intended

- Clean, disinfect and/or sterilise the product before first use
- Store products in such a way that they are not damaged
- Do not use damaged products
Discard damaged products immediately



Mirrors small, medium, large and lateral

Reprocessing instructions:

- Comply with international and national guidelines, standards and legal regulations as well as your own hygiene regulations for reprocessing
- It should be noted that successful reprocessing of this class I medical device can only be ensured after prior validation of the reprocessing process. The responsibility for this lies with the operator/reprocessor
- If no final sterilisation takes place, a virucidal disinfectant must be used
- For persons with infectious diseases, corresponding guidelines must be followed

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Our mirrors for dental photography are -certified.

Version 2.01, issue date: 20.11.2020, Balzers, Liechtenstein

Basic UDI-DI: 426071006MSP2

Restriction of reprocessing:

Care must be taken during reprocessing due to the thin mirror coating and the lacquered handles. Frequent, proper, manual reprocessing has little effect on the quality and life of the mirrors. Proper reprocessing with mechanical cleaning and disinfection can possibly lead to increased wear.

The end of the product life is normally determined by wear and tear from use. The mirrors must then be disposed of in the usual manner in dental practices.

General instructions for reprocessing:

- Instructions of the manufacturers of the cleaning media and disinfection media must be followed
- Reprocessing instructions must be followed

Cleaning: manually

- After use: Immediately soak mirrors with soft cloths in cleaning solution suitable for aluminium products and glass
- The mirrors must be completely covered by the solution
- Follow the concentration, exposure time and temperature of the cleaning solution exactly according to the manufacturer's instructions
- The cleaning solution should be suitable for manual cleaning (e.g. non-foaming)
- Clean the mirrors according to the recommendations of the Robert Koch Institute
- Change the cleaning solution according to the manufacturer's instructions or in case of visible contamination
- Ultrasonic cleaning is not recommended

Disinfection: manually

- Disinfect mirrors with suitable disinfectants according to the manufacturer's instructions
- Follow the concentration, exposure time and temperature of the disinfectant according to the manufacturer's instructions
- Remove the mirror from the disinfectant solution with fresh disposable gloves

Neutralisation/clear rinsing:

Rinse disinfected mirrors according to standard practice. Recommended instruction: Rinse with clean, sterile water to remove all disinfection residues.

Drying and functional testing:

The mirrors should be dried by dry rubbing or by compressed air after disinfection. After drying, the mirrors should be subjected to a functional test. Damaged mirrors must be disposed of.

Sterilisation:

The mirrors can be sterilised. After frequent sterilisation, impairment of full functionality may occur (e.g. partial detachment of the lacquer coating on the handle). Recommended sterilisation method:

In an autoclave (DIN EN ISO 17665-1)
 Recommended temperature: 121 °C (134 °C)
 Recommended pressure: 2 bar (3 bar)
 Holding time: ≥ 20 min (≥ 5 min)

Inspections:

Always verify that the mirrors are in good working order before use. Mirrors with damaged glass surfaces and coatings such as scratches, chipping, cracks, etc. may no longer be used. The mirrors must then be disposed of in the usual manner.

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Materials:

The materials used for the mirrors are a cast aluminium coated with silicone polyester (handle) and a glass coated with rhodium (mirror). The connection consists of a tested adhesive.

Risks:

The following risks may occur:

- Cutting injuries if the mirror is damaged or in people who have seizures, due to splinters and sharp edges
- Allergic reactions:
 - to aluminium, if handles are damaged
 - to adhesive, if not properly prepared

Restriction of use:

For persons with seizure susceptibilities, the mirrors should only be used together with jaw locks.

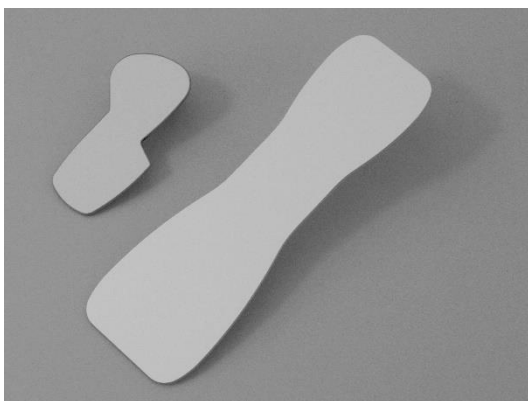
For persons with infectious diseases, the mirrors with handles should not be used. We advise the use of mirrors without handles instead. In any case, the preparation of mirrors without handles must be done carefully and according to standards.

Warranty:

The mirrors are made of high-quality materials and are subjected to a quality control before delivery. Should defects nevertheless occur, please contact your supplier or us immediately. We do not guarantee the suitability for the respective operation. This must be determined by the user himself/herself. We also accept no liability for accidental or resulting damage. We accept no liability if it can be proven that these instructions for use have been violated.

Attention: In case of use of the mirrors on persons with infectious diseases, we decline any responsibility for reuse.

If, contrary to expectations, serious incidents occur in connection with the mirrors, this must be reported to the competent authority (Swissmedic).



Mirrors without handle for occlusal and lingual photographs

Our mirrors for dental photography are **CE**-certified.

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