Eye Shields

Reprocessing Information

Item Code	Item Description
720C	**Eye Shields Clear**
720T	**Eye Shields Tinted**

THIS PROCESSING INFORMATION RELATES TO THE FRAMES ONLY. THE DETACHABLE LENSES ARE FOR SINGLE USE.

INTENDED USE

Eye Shields are intended to be worn by the patient or healthcare worker over the eyes to protect from body fluid splashes or debris during dental procedures. Tinted lenses provide additional protection to the patient from harsh overhead lights within the surgery. The eye frames are reusable.

According to Spaulding classification the device is semi-critical item.

REPROCESSING INSTRUCTIONS

The information in these instructions complies with the requirements of EN ISO 17664. Reprocessing must be carried out by qualified personnel only. The following procedure includes processes of cleaning, disinfection and sterilisation. All steps need to be performed together to obtain safe and effective reprocessing of the item. National directives, standards and specifications for the cleaning, disinfection and sterilisation of items must be adhered to.

WARNINGS

- Device must be cleaned, disinfected and sterilised according to these processing instructions.
- Devices are supplied non-sterile and must be processed before first use, and after every re-use.
- There is a risk of infection due to inadequate reprocessing. Thorough cleaning and disinfection are essential prerequisites for effective sterilisation.
- Reprocessing should be completed immediately after use to prevent contaminates drying out on item surfaces.
- All items used in reprocessing must be subject to regular maintenance and inspections.

Limitations & Restrictions on Processing

- Only trained professionals can use, disinfect, clean and sterilise the items. Always handle with care, wearing protective clothing, gloves and eye protection.
- Do not use dry heat, radiation, formaldehyde, ethylene oxide or plasma sterilisation methods.
- Do not re-use devices with signs of degradation or damage. Degradation is indicated by damage to the surface, cracks, fractures and deformation.

1. PREPARATION BEFORE PROCESSING

Perform visual inspection of the functionality of the device. Damage to the surface, bent parts, scratches, cracks, fractures, or deformation indicate the device is no longer suitable for use. If the device is connected to another instrument, it should be disassembled. One-part devices do not require any type of disassembly. Where disassembly is necessary, it should be self-evident.

2. CLEANING AND DISINFECTION

WARNING

- Do not use hot water (>40°C), strong alkalines (>pH 9), strong acids (<pH 4) or strong oxidizing agents to avoid any possible damage to the item.
- Always follow the concentration, temperature, residence time and post-rinsing specifications issued by the manufacturer of the cleaning and disinfectant agent.
- Only use CE marked cleaning and disinfectant agents with proven efficacy.

2.1 MANUAL CLEANING AND DISINFECTION

Accessories: disposable wipe, nylon brush, cleaning container, cleaning agent, disinfectant agent, disinfection bath, medical compressed air.

CLEANING

Prepare all accessories listed. Remove surface contamination with disposable wipe. Submerge the device into a cleaning container filled with a solution of tap water (of drinking quality) and cleaning agent, at the dilution rate and for the time specified in the agent's instructions. Use a nylon brush to clean the item surface, until all visible residues have been removed. Extra attention should be paid to difficult to reach places, where dirt may accumulate (joints, hinges). Thoroughly rinse the item under tap water (of drinking quality) for a minimum of 1 minute.

WARNING

- If there is still visible contamination after the cleaning process, cleaning must be repeated.

DISINFECTION

Fill the disinfection bath with the disinfectant agent. Fully submerge the cleaned item in the disinfection bath for the time specified in the agent's instructions. Remove the device from the disinfection bath. Thoroughly rinse the item with deionised water for a minimum of 1 minute.

DRYING

Dry at room temperature, using a lint-free cloth or medical compressed air. Ensure that difficult to reach areas have been dried.

2.2 AUTOMATED CLEANING AND DISINFECTION

WARNING

- Washer-disinfector drying temperatures must not exceed 100°C.

Accessories: washer-disinfector device (WD), basket insert, cleaning agent, disinfecting agent, lint-free cloth, medical compressed air.

Use only CE marked WD equipment validated under ISO 15883. Always follow the manufacturer's instructions for use. Place the item in a basket insert and load into the WD. Ensure devices do not come in contact with each other. Fill the WD

with cleaning agent/ disinfectant agent and select the cleaning and disinfection programme according to the WD and agents manufacturer's instructions for use. After the programme has finished running, remove the device from the WD.

DRYING

If additional manual drying is required, this must be performed using a lint-free cloth or using medical compressed air. Ensure that difficult to reach areas have been dried.

3. INSPECTION AND MAINTENANCE

The device must be carefully inspected after processing. Repeat cleaning & disinfection processes if visual inspection indicates that the item is not yet clean. Extra attention should be paid to difficult to reach places, where dirt may accumulate (joints, hinges). Visually inspect the item for damage to the surface, bent parts, scratches, cracks, fractures, or deformation indicating the item is no longer suitable for use.

4. PACKAGING

After processing, individually package the device in a disposable sterilisation pouch. Select appropriate size disposable sterilisation pouch for the device. Ensure the sealing is not under tension. Only package the device after it has been thoroughly cleaned and dried.

5. STERILISATION

WARNING

- Only the frames can be subjected to sterilisation. The detachable lenses are disposable after every use.
- Sterilisation temperatures must not exceed 138°C.
- Only cleaned, disinfected and dry devices can be sterilized.

Use only steam vacuum autoclaves which have been tested, validated and maintained in accordance with ISO 17665-1. Ensure that the manufacturers maximum load is not exceeded. Individual components must not contact to ensure the steam can circulate freely. Always follow the manufacturer's instructions for use of the autoclave.

Recommended parameters of steam sterilisation

Temperature	134°C (maximum 138°C)
Holding time	minimum 3 minutes
Drying time	20 minutes

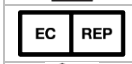
6. STORAGE

Packaged sterile devices must be protected against dust and moisture. Store in an environment between 5°C to 40°C. If the sterile packaging is compromised, the item must undergo reprocessing before use.

7. ADDITIONAL INFORMATION

The instructions provided have been validated by the manufacturer of the item as being capable of preparing an item for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. Any deviation from these instructions should be validated for effectiveness and potential adverse results. This requires verification and/or validation and routine monitoring of the process.

8. SYMBOLS

SYMBOL	DESCRIPTION
	Manufacturer
	Authorised Representative in the European Community
	Importer
	Distributor
	Indicates device is a medical device
	CE Marking, compliant with MDR 2017/745
	Not made with natural rubber latex

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