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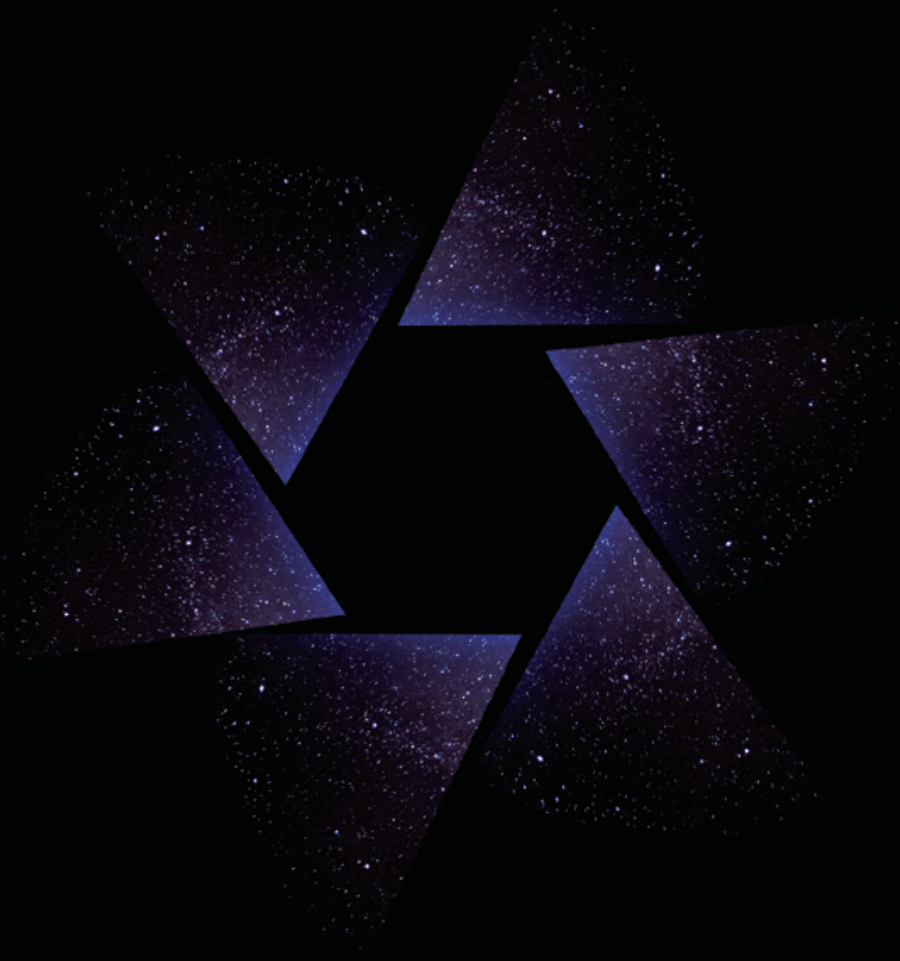

PHOTOGRAPHY FOCUS

— by DB Orthodontics —

Photography Focus Retractors

Retractor Small - DB04-0174A
Retractor Large - DB04-0175A
V Retractor Small - DB04-0178
V Retractor Large - DB04-0178L
Photo Lip Retractor - DB04-0154
Small Cheek Retractor - DB04-0183

Method: Sterilised using moist heat (ISO 17665)

Devices: Catalogue numbers and device description for the Photography Focus Cheek Retractors can be located on www.dbortho.com

These reprocessing instructions are in accordance with the requirements set out in BS EN ISO 17664 and apply to the reusable Photography Focus Cheek Retractors supplied by DB Orthodontics and intended for reprocessing in a healthcare setting. These reprocessing instructions have been validated as being capable of preparing the reusable Photography Focus Cheek Retractors for use. It is the responsibility of the user / hospital / healthcare provider to ensure that reprocessing is performed using the appropriate equipment and materials and also that personnel have been adequately trained in order to achieve the desired result; this normally requires that equipment and processes are and

routinely monitored. Any deviation from these instructions should be evaluated for the effectiveness to avoid potential adverse consequences.

Warnings

- Use a washer disinfector that meets the requirement of ISO 15883 parts 1 & 2.
- Use detergents and other processing chemicals in accordance with the manufacturer's instructions, including residual testing (as applicable).
- Saline and cleaning/disinfection agents containing aldehyde, chloride, active chlorine, bromine, bromide, iodine or iodide are corrosive and should not be used.
- Metal brushes and scouring pads must not be used during manual cleaning. Only use soft bristle brushes to aid with manual cleaning.
- Use of hard water should be avoided. Purified water should be used for final rinsing to prevent mineral deposits.
- Some sensitive materials can be damaged by higher alkaline solutions (pH > 10).
- Wear suitable personal protective equipment such as gloves, clothing and face covering (e.g., visor) as necessary when handling used devices or conducting manual cleaning and disinfection. When processing medical devices always follow local Health &

Safety procedures.

- It remains the responsibility of the end user/ hospital/healthcare provider to ensure that the reprocessing has achieved the desired result. This normally requires validation and routine monitoring of the process.

Intended Users

Photography Focus Cheek Retractors are intended to be used in a healthcare environment by appropriately healthcare professionals, who are familiar with, and have experience of the cheek retractors and techniques used.

Limitations on Processing

Photography Focus Cheek Retractors are suitable for reprocessing. When the maintenance instructions below are followed, the end of life for the cheek retractors is determined by wear and tear/damage and loss of functionality. It is important that users inspect the devices as instructed below before each patient use to verify that they are fit for purpose.

Initial Treatment at Point of Use

Do not allow blood and/or bodily fluids to dry on the cheek retractors; remove with a disposable cloth/paper wipe. It is recommended that the cheek retractors are processed through a validated washer disinfector immediately after

patient use. Handle contaminated cheek retractors with protective gloves.

Containment & Transportation

The used cheek retractors must be transported to the decontamination area for reprocessing in closed or covered containers to prevent unnecessary contamination risk. Where transport outside of the healthcare facility is required, containers meeting the requirements of UN3291 should be used.

Preparation before Cleaning

Select a pH neutral detergent (prepare all cleaning solutions at the concentration and temperature recommended by the detergent manufacturer). At least potable water should be used to prepare cleaning solutions. Remove any gross soil with a steady stream of lukewarm water (below 45°C), using a soft brush if necessary. The devices are suitable for use in an ultrasonic cleaner; in the case of devices with heavy or difficult to remove soiling such as bone debris. Water temperature should not exceed 45°C and a pH neutral detergent may be used at the concentration recommended by the manufacturer, including any necessary rinsing stages. A maximum frequency of 50kHz is recommended.

Rinse each cheek retractor thoroughly,

do not use saline or chlorinated solutions. Give special attention to any joints, slots, holes and grooves.

Automated Cleaning & Disinfection

Equipment: Validated Washer Disinfector meeting the requirements of EN ISO 15883 parts 1 & 2, with a pH neutral detergent.

- Lay the cheek retractors flat in a suitable basket with sufficient space from each other so that all surfaces can easily be contacted by the detergent and rinse water and drain sufficiently.
- The basket must be placed in the washer disinfector in such a way as to prevent mechanical damage e.g., washer disinfector spray arms should be free so as to avoid touching the cheek retractors.
- Select an appropriate cleaning cycle according to the following parameters:
  - An initial cleaning cycle below 45°C is recommended for optimal protein removal.
  - A main wash cycle using a pH neutral detergent at the manufacturer's recommended concentration and temperature, followed by a rinse cycle.
  - The final rinse cycle should be sufficient for thermal disinfection to AO ≥ 600, e.g. 90°C for 1 minute or 80°C for 10 minutes. Final rinse water should be performed using purified water, or to the requirements of national regulations.
  - A drying cycle sufficient to remove all

visible signs of water, ≤ 100°C.

- Cheek retractors should be completely dry prior to removing them from the washer disinfector.
- When removing the cheek retractors from the washer disinfector, carefully inspect the devices for visual check for cleanliness or damage. Repeat the cycle if any soil remains.

Maintenance & Inspection

Before preparing the cheek retractors for reprocessing all cheek retractors should be inspected. Visual inspection under good lighting of all parts of the cheek retractor should be performed to check for visible soiling, damage, corrosion and wear. Particular attention should be paid to:

- Recessed features such as, slots, holes and grooves where soiling could accumulate.

Discard any cheek retractors that are damaged or worn. Cheek retractors must be completely dry prior to pouching or wrapping to avoid surface discolouration/ damage and to avoid compromising the sterilization process.

Packaging

All cheek retractors are to be packed following local protocol in accordance with relevant standards or decontamination manual process.

Packaging should ensure sterility of the cheek retractors until opened for use at the sterile field and permit removal of contents without contamination. Place cheek retractors into suitable, validated packaging which has been validated for steam sterilization (temperature resistant up to 141°C/286° F) i.e., AISI AAMI, ISO 11607 compliant, medical grade single-use wraps or pouches before loading into a perforated general instrument autoclave tray. Do not exceed sterilizer's maximum load when sterilising multiple devices in the autoclave. Only used validated loading patterns.

Sterilization

Use only the sterilization procedure below. Other sterilization procedures have not been validated for their ability to achieve sterility or to prevent damage to the cheek retractors, and are solely the responsibility of the user.

- Use a suitably approved autoclave (e.g., CE marked for medical device sterilization).
- The autoclave must be validated according in accordance with ISO 17665-1, CFPP 01-01, Health & Technical Memoranda or other equivalent National / local regulations and guidelines.
- Do not use the flash sterilization procedure.
- Cheek retractors must be placed in suitable, validated packaging (see

packaging section above) before being loaded into a perforated general sterilization tray.

- Use one of the following sterilization exposure times at the sterilization temperature:

Fractioned Vacuum Autoclave:
Temperature: 121°C, Exposure time: 15 minutes, 132°C, Exposure time: 4 minutes, OR Temperature: 134°C, Minimum exposure time: 3 minutes.
Cool down time/dry time: 20 minutes.

Note: Take care not to exceed the maximum temperatures specified by the packaging manufacturer.

Note: The final responsibility for validation of sterilization techniques and equipment lies directly with the healthcare facility. To ensure optimal processing, all cycles and methods should be validated for different sterilization chambers, wrapping methods and/or various load configurations.

Storage

The shelf life is dependent on the sterile barrier employed, storage, environmental and handling conditions. A maximum shelf life for sterilised medical devices should be defined by the healthcare facility. Store the cheek retractors after sterilization in a dry and dust free place.

Sterility can only be maintained if the devices remain sealed or wrapped in their undamaged packaging.

Limitation of Liability

Except where prohibited by law, DB Orthodontics will not be liable for any loss or damages arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability. This limitation does not apply to third party personal injury claims.

Returning Products to us

Products returned to us after use must have a decontamination certificate which testifies that each cheek retractor has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a delay of your enquiry being processed.

References

BS EN ISO 17664 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices. HTM 01-01 Management & decontamination of surgical instruments (medical devices) used in acute care BS EN ISO 15883: Parts 1 & 2: Washer disinfectors.

Serious Incidents

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.

Manufacturer

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Photography Focus Cheek Retractors are in conformity with Regulation (EU) 2017/745 and conform to the General Safety and Performance Requirements set out in Annex I of Regulation (EU) 2017/745. The instructions provided above have been validated by DB Orthodontics for the Photography Focus Cheek Retractors for their use and reprocessing. It remains the responsibility of the processor to ensure that processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the processes as well as suitable maintenance and validation of the equipment used.

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