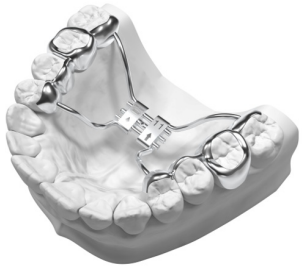

db orthodontics DB Ortho Instruments Instructions

collaboration precision innovation
Recommended sterilization instructions for the range of DB instruments

Contents

DB Ortho Instruments

General Instructions for Care, Handling and Reprocessing of non-sterile DBO Instruments

STERILE	

Method: Sterilised using moist heat (ISO 17665
Devices: Catalogue numbers and device description for the DBO Instruments can be located on **https://dbortho.com/**. These reprocessing instructions are in accordance with the requirements set out in BS EN ISO 17664 and apply to the reusable DBO hand-held instruments 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 DBO instruments 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).
- If the devices are used in conjunction with other devices, such as powered handpieces, ensure the companion devices are reprocessed according to the manufacturer's instructions. These instructions only apply to the DB Orthodontics devices above.
- 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

DBO instruments are intended to be used in a healthcare environment by appropriately healthcare professionals, who are familiar with, and have experience of the instruments and techniques used.

LIMITATIONS ON PROCESSING

DBO instruments are suitable for reprocessing with no limits on the number of reprocessing cycles. Repeated processing according to these instructions has minimal effect upon these reusable devices. When the maintenance instructions below are followed, the end of life for instruments 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 instruments; remove with a disposable cloth/ paper wipe.
It is recommended that the instruments are processed through a validated washer disinfector immediately after patient use. Handle contaminated instruments with protective gloves.
CONTAINMENT & TRANSPORTATION

The used instruments 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. 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 instrument thoroughly, do not use saline or chlorinated solutions. Give special attention to any hinges, 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 instruments flat in an open position; 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 instruments.
- Select an appropriate cleaning cycle according to the following parameters:
  o An initial cleaning cycle below 45°C is recommended for optimal protein removal.
  o A main wash cycle using a pH neutral detergent at the manufacturer's recommended concentration and temperature, followed by a rinse cycle.
  o 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.
  o A drying cycle sufficient to remove all visible signs of water, ≤ 100°C.
- Instruments should be completely dry prior to removing them from the washer disinfector.
- When removing the instruments from the washer disinfector, carefully inspect the devices for visual check for cleanliness, damage or corrosion. Repeat the cycle if any soil remains.

MAINTENANCE & INSPECTION

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

- Recessed features such as hinges, joints, slots, holes and grooves where soiling could accumulate.
- Cutting surfaces that can sustain damage or bluntness.

Discard any instruments that are damaged or worn and are outside the warranty period. Instruments must be completely dry prior to pouching or wrapping to avoid surface discolouration/corrosion damage and to avoid

compromising the sterilisation process. Cutting instruments that are frequently used should be reconditioned every six (6) to nine (9) months. If articulated joints do not move smoothly, lubricate prior to sterilisation with a medical grade lubricant. The lubricant must be biocompatible and suitable for steam sterilisation.

PACKAGING

All instruments are to be packed following local protocol in accordance with relevant standards or decontamination manual process. Packaging should ensure sterility of instruments until opened for use at the sterile field and permit removal of contents without contamination. Place instruments into suitable, validated packaging which has been validated for steam sterilisation (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 instruments in the autoclave. Only used validated loading patterns.

STERILISATION

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

- Use a suitably approved autoclave (e.g., CE marked for medical device sterilisation).
- 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 sterilisation procedure.
- Instruments must be placed in suitable, validated packaging (see packaging section above) before being loaded into a perforated general instrument tray.
- Hinged instruments should be sterilised with the hinge open.
- Use one of the following sterilisation exposure times at the sterilisation 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 sterilisation techniques and equipment lies directly with the healthcare facility. To ensure optimal processing, all cycles and methods should be validated for different sterilisation 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 instruments after sterilisation in a dry and dust free place. Sterility can only be maintained if the devices remain sealed or wrapped in their undamaged packaging.

WARRANTY

- Instruments are warrantied to be free from defects in material and workmanship for the expected life of the instrument. (Workmanship includes material breakage such as weld/braze failure ofinserted instruments). Warranty does not include regular sharpening of cutting instruments or routine maintenance/ refurbishment of instruments.

- DB Orthodontics's sole responsibility shall be (at its own discretion) to repair, replace or credit the instrument in the event of any claimed defects. Adherence to recommended cleaning, sterilisation and lubrication practices will help ensure optimum instrument performance.
- Warranty does not cover routine maintenance, sharpening or reconditioning.
- Warranty claims or service request should be forwarded directly to: Instrument Repair Department. returns@dbortho.com

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.

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

DB Orthodontics Ltd
Ryefield Way, Silsden, West Yorkshire, BD20 0EF, England
DBO Instruments, 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 DBO instruments 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.

SYMBOLS KEY

EC Rep Symbol

MD Symbol
Medical device


IFU Symbol
Consult instructions for use or consult electronic instructions for use


CE Symbol
Class I medical device


Black factory symbol
Manufactured by.

Non Sterile
Non sterile = 
Sterilize before use

SCAN THE QR CODE

TO VIEW OUR
MULTI-LANGUAGE
INSTRUCTIONS FOR USE

https://dbortho.com/pages/downloads

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EC REP

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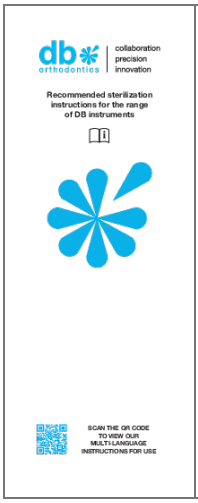
Documents / Resources



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DB Ortho Instruments, DB Ortho, Ortho Instruments, Instruments, Ortho

References

- **User Manual**