infinitas™

Instruments & Aluminium Tray - Non-Sterile

NON-STERILE

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General Instructions for Care, Handling and Reprocessing of DB Orthodontics non-sterile Infinitas Instruments and the aluminium tray.

Method: Sterilized using moist heat (ISO 17665)

DESCRIPTION

Product Code	Item Description
DB10-0020	Infinitas Standard Handle
DB10-0021	Infinitas Screwdriver Standard Insert
DB10-0025	Infinitas Mini Screwdriver (Manual)
DB10-0022	Infinitas Mucotome Standard Insert
DB10-0023	Infinitas Cortical Punch Standard Insert
DB10-0026	Infinitas Screwdriver Mini Insert
DB10-0027	Infinitas Mucotome Mini Insert
DB10-0028	Infinitas Cortical Punch Mini Insert
DB10-0029	Infinitas Aluminum Tray

These reprocessing instructions are in accordance with the requirements contained in BS EN ISO 17664 and apply to the non-sterile Infinitas, reusable hand-held Instruments and the reusable aluminium tray supplied by DB Orthodontics which are intended for reprocessing in a healthcare setting.

The instruments and the aluminium tray are reusable devices and as such should be reprocessed according to the instructions provided below.

These reprocessing instructions have been validated as being capable of preparing the Infinitas instruments and the aluminium tray 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 manufacturers 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 relevant manufacturers' instructions. These instructions only apply to the DB Orthodontics devices outlined above.
- The Standard Handle (DB10-0020); should be disconnected from the inserts (DB10-0021, DB10-0022, DB10-0023) prior to processing.
- 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.
- The Infinitas instruments and aluminium tray are intended to be used in a healthcare environment by appropriately healthcare professionals, who are familiar with, and have experience of the devices and techniques used.

INTENDED USE

Infinitas instruments and aluminium tray are supplied non-sterile. They are intended to be processed before use.

INTENDED USERS

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

LIMITATIONS ON PROCESSING

Infinitas Instruments and aluminium tray are however 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 or aluminium tray; remove with a disposable cloth/paper wipe. It is recommended that the instruments and aluminium tray are processed through a validated washer disinfector immediately after patient use. Handle contaminated devices with protective gloves.

CONTAINMENT & TRANSPORTATION

The used instruments and aluminium tray 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. The Standard Handle (DB10-0020); should be disconnected from the inserts (DB10-0021, DB10-0022, DB10-0023) prior to processing.

Remove any gross soil with a steady stream of lukewarm water (below 45°C), using a soft brush if necessary. Special attention should be taken when washing part numbers DB10-0022, DB10-0023, DB10-0027 and DB10-0028; as these parts come into contact with bone and tissue.

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 instrument 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 instruments 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.

- Wash the aluminium tray separately in another suitable basket and do not stack them – ensure there is sufficient space for contact with the detergent and water and to drain sufficiently.
- The baskets 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 and aluminium tray.
- 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 manufacturers 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.
- Instruments and aluminium tray should be completely dry prior to removing them from the washer disinfector.
- When removing the instruments and aluminium tray 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 and the aluminium tray for reprocessing all instruments and the aluminium tray should be inspected. Visual inspection under good lighting of all parts of the instruments and aluminium tray should be performed to check for visible soiling, damage, corrosion and wear.

Particular attention should be paid to:

- Recessed features such as 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. The aluminium tray should be inspected to ensure all components fit in the box. Instruments and aluminium tray must be completely dry prior to pouching or wrapping to avoid surface discolouration/ corrosion damage and to avoid compromising the sterilization 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 sterilization with a medical grade lubricant. The lubricant must be biocompatible and suitable for steam sterilization.

PACKAGING

Instruments and the aluminium tray are to be packed following local protocol in accordance with relevant standards or decontamination manual process. Packaging should ensure the sterility of instruments and aluminium tray until opened for use at the sterile field and permit removal of contents without contamination.

Place instruments and the aluminium tray 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.

The aluminium tray is intended to hold all the required instruments together during the sterilization process.
Note: If the aluminium tray is not used; the instruments should be packaged individually or into a suitable all-purpose sterilization basket.

Do not exceed sterilizer's maximum load when sterilising multiple instruments 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 instruments or aluminium tray 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.

- Infinitas instruments and the aluminium tray must be placed in suitable, validated packaging (refer to 'Packaging' section above).
- 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 storage, environmental and handling conditions. A maximum shelf life for sterilized medical devices should be defined by the healthcare facility. Store Infinitas instruments or aluminium tray 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 INSTRUMENTS TO US

Products returned to us after use must have a decontamination certificate which testifies that each instrument and/or aluminium tray 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
EN ISO 17665 part 1 Sterilization of health care products – moist heat

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.

The instructions provided above have been validated by DB Orthodontics for the reusable Infinitas Instruments and reusable aluminium tray 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.


Consult Instructions for use.

Medical Device


Single Use Only

LOT Number


DO NOT USE IF PACKAGING IS DAMAGED