Manufacturer: Altomed Limited.

Altomed Ltd. 2 Witney Way, Boldon, Tyne/Wear. NE35 9PE. Tel: 0191 519 0111 Fax: 0191 519 0283

Device(s):	All reusable Diamond Knives made by Altomed Limited

IMPORTANT The instructions provided below have been validated by Altomed as being capable of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the processing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

1. Introduction

1. These procedures should be followed when cleaning and sterilizing reusable Diamond Knives made by Altomed Limited. These procedures should be followed in conjunction with any existing Hospital Cleaning and Sterilization procedures. These devices should only be monitored, controlled, handled, cleaned and processed by suitably trained and qualified personnel under an approved quality management system such as ISO 9001 or ISO 13485. Processing systems used must be able to sterilize devices to EN 556. Follow guidelines in HTM2010 and HTM2030. Use HTM2031 if necessary (see Limitations on Processing).

2. WARNINGS:

Note: Do not drop the Diamond Knife! Handle as being VERY FRAGILE

Note: The blade should be retracted at all times except when being used or cleaned

Single Use Symbol
Do not re-use or reprocess

CE marked products display this symbol

1. The base of the blade and any cannulations require special attention during cleaning.
2. The blade should be retracted when the device is being passed between people.
3. Do not exceed 140°C. Initial rinsing/cleaning temperatures should not exceed 35°C as temperatures above this may cause coagulation of proteinaceous substances.
4. Do not process Diamond Knives in an Ultrasonic Cleaner as this will result in stripping away the special adhesives that help to the secure the diamond blade in place.
5. Follow hospital/facility Health & Safety protocols at all times (e.g. C.O.S.H.H, P.P.E. etc.)
6. Follow hospital/facility and MHRA Guidance to control the processing of the devices.
7. Follow hospital/facility approved procedures or recommendations in the *"Transmissible Spongiform Encephalopathy Agents: Safe Working And The Prevention Of Infection"* compiled by the Advisory Committee on Dangerous Pathogens Spongiform Encephalopathy Advisory Committee for processing devices that have been exposed to unconventional slow viruses or prion diseases such as Creutzfeldt Jakob Disease (C.J.D), Kuru, Gerstmann-Straussler-Scheinker Syndrome (G.S.S.), Fatal Familial Insomnia (F.F.I.), Scrapie, Bovine Spongiform Encephalopathy (B.S.E.) etc.
8. Protect from contamination by processing in a suitably controlled environment.
9. Care should be taken when the blade is in the vicinity of other instruments as touching the diamond cutting edge against forceps etc. is sufficient to damage the blade.
10. Do not process rusty or damaged instruments with good instruments or stainless steel with normal steel or iron instruments.
11. **General note: Do not re-use or reprocess single use devices**
12. Follow the instructions for use supplied by all the machine and detergent manufacturers.
13. Instruments should not be exposed to Bromine, Iodine, Calcium Chloride, Calcium Hypochlorite, Sodium Hypochlorite or Chlorhexidine or spirit based fluids. Any chemicals used should be Tenzide free.
14. Only use CE marked chemicals specifically approved and labelled for use with medical devices. Washer/disinfectors and Ultrasonic Cleaners should also be CE marked.

3. Limitations on reprocessing

1. Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use, processing or handling. Exposure to strong acid or alkaline may reduce the working life of instruments.
2. If the device is knocked against other instruments, dropped or mishandled the blade can chip or snap. If the blade appears to be blunt, this will mean that the cutting surface of the blade has been chipped. Diamond knives will not normally go blunt through normal use.
3. If the diamond blade comes loose it is most likely due to the cleaning process not being suitable for the device. These devices should not be processed in Ultrasonic Cleaners.

Processing Instructions

4. Point of use

Symbols denoting instructions

1. Remove excess soil by rinsing in purified water as soon as possible after use. It is recommended to use a proprietary Diamond Knife Cleaning Block *e.g Altomed code 40-462* follow the manufacturer's instructions to clean the blade. Do not apply forces to the blade!
2. Care must be taken to ensure fingers are kept away from any sharp surfaces and that any delicate tips are cleaned with the utmost care.
3. Do not allow contaminants to dry on the device. *Altomed recommend the use of a suitable Enzymatic preparation solution such as Ruhof Prepzyme XF to keep debris moist*
4. Pack devices in a suitable container e.g. *Microwash Tray or A9202 Tray* , to prevent damage to instruments during handling. Care must be taken to prevent unwanted contamination.
5. Follow hospital/facility approved procedures for transporting contaminated devices.

5. Preparation for cleaning

1. Throughout the whole cleaning process remove any debris by applying force to the debris and not the blade wherever possible. Clean the device as soon as possible after use.
2. Ensure all staff who will be processing the knives are trained in handling them.
3. Flush any devices with a lumen using a Quickrinse Machine, syringe etc if applicable
4. Ensure staff who will be processing the devices are trained in handling the devices

6. Cleaning 1: Equipment and Chemicals

1. Equipment: Chemical bath and Washer /Disinfector CE marked and approved for use by the hospital/facility with a validated cycle. Processing tray, *e.g.. Microwash or A9202*
2. Detergent: CE marked pH neutral Endozymatic detergent, *Altomed recommend Ruhof Endozyme AW Triple Plus.* Any chemicals used should be CE marked and be specifically designed and labelled for use with medical devices.

7. Cleaning 2: Initial Cleaning

1. Prepare a chemical bath using the detergent and sterile purified water if necessary. The temperature of the chemical bath should not exceed 35°C. *Altomed have validated a bath bath using the Ruhof Endozyme Triple Plus at a mixture of 4ml chemical to 1litre of water with a minimum exposure time of two minutes.* The chemical manufacturers instructions for use and those in HTM2010 and HTM 2030 should be followed where applicable.
2. Expose the diamond blade by retracting the protective cover. Keep the device fully immersed in the solution, carefully agitate to ensure any visible contamination has been removed. A Diamond Knife Cleaning Block can be used if necessary, follow manufacturers instructions. Ensure exposure to the solution is for the recommended time as specified by the manufacturer of the detergent. Do not apply force to the blade! Ensure solution reaches all surface areas of the device for the recommended exposure time.
3. Carefully dry using hot air dryer or drying cabinet. If necessary use medical grade compressed air. Retract the blade after processing by pulling forward the protective cover.
4. Inspect the device as outlined in Step 11 before proceeding to final cleaning at Step 8.

8. Cleaning 3: Washer / Disinfector

Note:
Do not process Diamond Knives in the Ultrasonic Cleaner

1. Place instruments into a suitable container *(e.g. Microwash or A9202 Tray)* to protect them from handling damage that can occur during processing.
2. Load the Diamond Knife with the blade retracted. If the blade is exposed during the cleaning cycle this may damage the delicate structure of the blade.
3. Load the machine as recommended in the hospital/facility procedures, so that the load configuration does not impede the cleaning process. Keep heavy objects at the bottom of the trays, do not overload baskets and do not let instruments touch each other.
4. Where available use machine attachments to flush the lumen inside cannulated devices. If not available flush lumens with the detergent prior to processing to remove organic matter (e.g. Quickrinse Machine, syringe etc.) then rinse in purified water to remove any residues.
5. Run a cycle that has been approved and validated by the hospital/facility. The initial rinse should be at or below 35°C, followed by a hot water disinfection rinse where the surface of the device should reach 71°C for a minimum of 3 minutes, 80°C for 1 minute or 90°C for 1 second (HC(91)33 and BS2745). *Altomed have validated a cycle with the following parameters: 5 minute pre-wash at 20°C followed by an Endozyme wash at 50°C for 5 minutes, a 1 minute rinse at 60°C and a thermal disinfection cycle of 90°C for 6 minutes;* however it is recommended to follow HTM Guidance where applicable.
6. When unloading check devices including the base of the blade, holes etc. for complete removal of visible soil. Ensure the instruments are dry before further processing.
7. If necessary repeat cycle, initial cleaning steps or carry out manual cleaning.

9. Cleaning 4: Manual

1. Use a double sink system dedicated only for cleaning instruments - DO NOT use a hand wash basin. Ensure the water temperature is warm but does not exceed 35°C. Use a hospital/facility approved detergent diluted as necessary to the manufacturer's guidelines in first sink. Detergent used should be CE marked and designed specially for medical devices.
2. Fill second sink with purified water. Carefully immerse item in the solution and displace any trapped air. Ensure solution reaches all areas of the device including any lumened surfaces.
3. Keeping the device fully immersed in the agitate or irrigate the item to dislodge any visible dirt. Do not use steel wool, abrasive powders or hard bristled brushes.
4. Pay particular attention to joints or areas where debris may collect e.g. base of the blade. If touching the blade, handle with extreme care.
5. Remove from the solution and drain over the detergent filled sink. Check to ensure the device is visibly clean. If necessary use a proprietary Diamond Knife Cleaning Block to remove stubborn dirt, follow manufacturer instructions for use. Use these devices with care.
6. Transfer knife to the second sink. Rinse device thoroughly with sterile distilled water, ensure device is fully immersed and any residues are removed. Flush any cannulated devices with sterile purified water. Remove from the rinse water and drain.
7. Carefully dry using hot air dryer, drying cabinet or medical grade compressed air.
8. Retract the blade after processing by pulling forward the protective cover.

10. Special note:

1. Dispose of contaminated Diamond Knife Cleaning Blocks as biohazard waste under the manufacturers and/or hospital/facility risk assment approved and controlled procedures.
2. Care should be taken to ensure there is no unwanted cross contamination.

11. Inspection/ maintenance

1. Visually inspect all surfaces, cannulations etc. for complete removal of all debris such as organic matter and any chemical residues.
2. Pay particular attention to the base of the blade where residues can build up.

11. Inspection / maintenance - continued

Note:
Check all devices against either a master sample or the drawings shown in the Altomed Catalogue. Contact Altomed if in any doubt

3. Inspect each device as follows; contact Altomed if in any doubt as to suitability:
   Blade - Check under a microscope for snapped blades, chips, cracks or debris. The blade should be aligned correctly and secure without movement.
   Finish - Should be clean with no staining, debris or residues. All markings should be clear and easily visible. Staining may be removed by using a specially designed cleaning agent *Altomed recommend Ruhof Surgi-Stain,* follow manufacturer's instructions for use then clean the device thoroughly using an automated or manual process as available to remove any residues.
   Structure - No scratches, nicks, bends, distortions, cracks, flaking, pitting or other signs of physical or handling damage.
   Movement - Smooth without grating, scratching, jerking or excessive play.
   Locking Mechanisms - Should open and closed easily, check also for any cracks in the protective sleeve. The protective sleeve should fully cover and protect the diamond blade.
   Tips - Check the integrity and cutting ability of tip (see Cutting Edges).
   Assemblies - All interlocking and detachable parts should fit easily and correctly without the need to apply any excessive force.
   Cutting edges - Should give a clean cut along the length of the blade. Test by cutting damp tissue paper: ensure cut is clean, along full length of blade and does not pull at tissue fibres.
   Lubrication - When necessary instruments should be lubricated on all moving parts after cleaning. Follow the Lubricant Manufacturer's instructions. Any lubricants used must be specifically designed, CE marked and labelled for use with medical devices, *Altomed recommend the Ruhof Premix-Slip lubricant.*

12. Packaging

Lot Number Symbol


Use By Symbol

1. Use hospital/facility approved and validated protocols and packing material, e.g. pouches or wraps. Protect devices from handling damage (e.g. Microwash Tray) during processing.
2. Ensure packing is large enough to prevent pressure on the seals. *Altomed recommend products to BS 868.* Ensure traceability with LOT number and shelf life with use by date.
3. Pack the Diamond Knife so that the blade is withdrawn in the protective shield.

13. Sterilization:

Ethylene Oxide

Moist Heat

Radiation

Common Sterile Symbols

1. Use a hospital/facility approved and validated protocol and sterilize to EN556. Ensure all equipment and systems are controlled, maintained and calibrated, e.g. HTM2010 HTM2030
2. Ensure all devices are suitably packed in a protective barrier (e.g. pouch, wrap) to maintain sterility after removal from the sterilizer. *Altomed recommend using materials to EN868.*
3. *The preferred sterilization cycle and one that has been validated by Altomed is a standard Autoclave cycle operating between 134°C and 137°C with a 3 minute holding time.* These conditions may vary, see also Table 5 in HTM2010 for suitable variations if required.

14. Storage


Protect device from rain and direct sunlight

1. Stores should ensure optimum quality conditions are maintained. Devices should be kept away from floors, walls, and ceilings. Store in a clean, dry well ventilated environment.
2. Sterile devices should be clearly identified with use by dates and be segregated from non-sterile devices where appropriate. Keep sterile products out of direct sunlight, at normal room temperature and humidity. Ensure all devices are dry before storage. Reject any devices devices in wet or damaged packing. **NEVER STORE INSTRUMENTS WHEN WET.**

15. Damaged devices and disposal

1. If a device fails inspection protocols it should be rejected. If in any doubt as to the integrity of a device after decontaminating, send to the Altomed Repairs Department for evaluation with a signed Decontamination Certificate. If the device is beyond repair then it should be decontaminated and wrapped to protect handlers from sharp edges. It should then be disposed of by following hospital/facility Risk Assessment approved procedures.