Sterlisation and Instructions for Use

Product: Arkansas Stones
Classification: Class 2a Medical Device – (multi-use device)

Arkansas stones are used by the Dental Surgeon for grinding and finishing of, filling materials and composite filling materials.
Arkansas stones are Class 2a Medical devices and are for use in the mouth only by (or under the instruction of) a qualified dental professional. They are manufactured in accordance with the standard ISO 1797, and should only be used in conjunction with a rotary hand piece that conforms to ISO 14457 the operator should ensure that the rotary instrument is correctly installed in the hand piece prior to commencement of any procedure.

PROPER USE

- Only use hand piece, angles and turbines that are technically and hygienically flawless, maintained and cleaned,
- Turbine and hand piece must be concentric and true running.
- The instruments must be clamped as deeply as possible.
- Avoid tilting or levering because of the increased risk of breakage.
- Instruments that are deformed or no longer run true should not be used and must be disposed of.
- Always wear safety goggles.
- Wear a face mask to prevent biological transfer
  Incorrect use produces poor results and increases the risk. These products must only be used by qualified staff.

SAFETY PRECAUTIONS

All these dental instruments were developed and manufactured for their specific dental surgical application. Incorrect use may harm tissue, cause premature wear, destroy the instruments and endanger the operator, patient or third parties.

PRESSURE

- Excessive pressure must be avoided at all times.
- Excessive pressure may damage the instruments. Heat build up is also increased.

DISPOSE OF WORN INSTRUMENTS

- Fractured and incorrectly shaped products cause vibration.
- Bent or non-concentric rotary instruments must also be disposed of.

Worn or damaged instruments induce the user to exert more pressure, which increases the working temperature. This may injure the pulp or tooth.

STORAGE, DISINFECTION, CLEANING AND STERILISATION

SCOPE

These instructions are applicable to the processing of PABLO ULLRICH Arkansas Stones dental rotary instruments before first and each subsequent use. They are dental rotary instruments and are supplied mechanically clean but are not sterile. They should therefore be sterilized before use. Arkansas Stones are multi use devices and the instructions therefore apply to processing before every use.

WARNINGS

Used rotary instruments should be considered as contaminated and appropriate handling precautions should be taken during processing. Gloves, eye protection and a mask should be worn. Other measures may be required if there are specific infection or cross-contamination risks from the patient.

CONTAINMENT AT THE POINT OF USE

Unless there is specific infection or cross-contamination risks, there are no special requirements for containment. The instruments can be transported wet or dry and should be protected from damage to the working part. If transported wet there is an increased chance of staining or corrosion. Prolonged storage in disinfectant solutions may result in corrosion and should be avoided.

Delay in processing must be kept to a minimum to avoid contaminants drying thereby making cleaning more difficult.

PREPARATION FOR CLEANING

There are no special requirements unless infection controls require the use of a disinfectant, in which case a disinfectant agent validated for processing of dental prophy brushes must be used and the disinfectant manufacturers' instructions must be followed.

CLEANING

Auto cleaning is the preferred method and should use only validated washer disinfectors and appropriate agents validated for use on dental prophy brushes with the selected machine. Follow the washer disinfector and the cleaning agent manufacturers' instructions.

If hand cleaning is the only available option, the Arkansas Stones should be cleaned in a sink reserved for the purpose. Rinse the Arkansas Stones under running cold water and, keeping them immersed, brush thoroughly away from the body using a neutral cleaning or cleaning/disinfecting agent validated for use on dental products. Follow the agent manufacturers' instructions. Care should be taken to avoid spreading contaminants by spraying or splashing during the brushing process. Use wire brushes with caution as brass particles may result in galvanic corrosion and steel particles may cause discolouration.

After cleaning inspect the Arkansas Stones, with the aid of magnification if necessary, to ensure that all contamination has been removed. Repeat the cleaning process if necessary.

DRYING

Dry the Arkansas Stones using paper towelling.

INSPECTION

Inspect the Arkansas Stones, with the aid of magnification if necessary, and discard any damaged or corroded instruments.

PACKAGING FOR STERILIZATION

If using a **vacuum autoclave** pack the Arkansas Stones in dedicated instrument trays or pouches validated for sterilization.

If using a **non-vacuum autoclave** the Arkansas Stones should not be packed or wrapped but be contained in dedicated bur stands with perforated lids.

STERILIZATION

Autoclave the instruments for a holding time not less than three minutes at a temperature of 137ºC.

The holding time is the minimum time for which the minimum temperature is sustained.
The autoclave manufacturer's instructions must be followed. In particular care must be taken not to exceed the maximum recommended load for the autoclave.

STORAGE

The Arkansas Stones should be stored in the sterilization container (bur stand or pouch) until required. Containers or pouches must be dry before opening to avoid recontamination of the contents with water. Storage should be in dry, clean conditions and at ambient temperature.

VALIDATION

These processes have been validated as being capable of preparing PABLO ULLRICH Arkansas Stones for use. It remains the responsibility of the processor to ensure that the processing as actually performed using the equipment, materials and personnel in the processing facility achieve the required results. This may require validation and monitoring of the process. Any deviation from these instructions should be properly evaluated for effectiveness and potential adverse results.