


| | | | |
|--|---------------------------|--|-------------------|
|  | Gebrauchsanleitung | TD Kapitel 7 | Seite: 1 von 4 |
| | | Revisionsstand: 2 / 20.09.2013 | |
| Produktbezeichnung: zahnärztliche Bürsten, SIC | | | |

Sterilisation and Instructions for Use

Product: SiCA Junior Cup and KS Occlusal Brushes

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

SiCa (Silicon Carbide) Occlusal Polishing Brushes (Junior Cup Brushes and Pencil Brushes) RA shanks.

PABLO ULLRICH SiCa (Silicon Carbide) Occlusal Polishing Brushes are dental rotary instruments for use by the Dentist or Hygienist for prophylaxis polishing of restorations and natural teeth. Polishing paste is not necessary as the filaments are loaded with fine silicon carbide polishing particles for high lustre finish. These instruments 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

These dental instruments were developed and manufactured for their specific polishing 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 working sections of rotary polishing instruments or damage the fill material. Heat build up is also increased.

Excessive pressure may cause overheating which injures the pulp or damage brush material. In extreme cases, the instrument may even break, which may cause injury

RECOMMENDED SPEEDS

| | | | |
|--|-----------|------------------|---------------|
| Erstellt: | Freigabe: | Ersetzt Ausgabe: | Verteilt an: |
| P. Ullrich 20.09.2013 | | 01.10.2009 | P. Ullrich |
| Datei: UP PLM SiCA Junior Cup and KS Occlusal Brushes 2013 | | | Seite 1 von 4 |

Sterilisation and Instructions for Use

- The maximum speed is 5,000 rpm. The optimum speed in use is 3,000 rpm for the best work results and to increase the service life of the instrument.
- If you exceed the maximum permitted speed, the instrument tends to vibrate, which can cause damage to the shaft and/or make the instrument break, with a risk to the user, the patient or third parties. Failure to comply with the maximum permitted speed produces an increased safety risk.

DISPOSE OF WORN INSTRUMENTS

- Worn or damaged brushes may cause vibration.
- Bent or non-concentric instruments must also be disposed of.

Worn or blunt prophy brush rotary instruments may 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 dental rotary instruments (SiCa Occlusal Polishing Brushes) before first use and each reuse. Dental rotary instruments are supplied mechanically clean but are not sterile.

WARNINGS

Used instruments should be considered as contaminated and appropriate handling precautions should be taken during reprocessing. 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.

LIMITATIONS OF PROCESSING

Reprocessing will have little effect on PABLO ULLRICH SiCA brushes. The end of life is determined by wear and damage in use and the brush should be inspected for defects and/or wear during the preliminary cleaning process.

CONTAINMENT AT THE POINT OF USE

Unless there is specific infection or cross-contamination risks, there are no special requirements for containment. The brushes 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 reprocessing 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 brushes must be used and the disinfectant manufacturers' instructions must be followed.

| Erstellt: | Freigabe: | Ersetzt Ausgabe: | Verteilt an: |
|--|-----------|------------------|---------------|
| P. Ullrich 20.09.2013 | | 01.10.2009 | P. Ullrich |
| Datei: UP PLM SiCA Junior Cup and KS Occlusal Brushes 2013 | | | Seite 2 von 4 |

Sterilisation and Instructions for Use

CLEANING

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

If hand cleaning is the only available option, the burs should be cleaned in a sink reserved for the purpose. Rinse the brushes 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 burs. 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 brushes, with the aid of magnification if necessary, to ensure that all contamination has been removed. Repeat the cleaning process if necessary.

DRYING

Dry the brushes using paper towelling or dry heat not exceeding 140°C.

INSPECTION

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

PACKAGING FOR STERILIZATION

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

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

NOTE: National legislation may require that burs are wrapped in pouches for processing in either type of autoclave.

STERILIZATION

Autoclave the instruments for a holding time not less than three minutes at a temperature of 134°C.

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 brushes 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

It remains the responsibility of the processor to ensure that the reprocessing as actually performed using the equipment, materials and personnel in the reprocessing facility achieve the required results. This may require

| Erstellt: | Freigabe: | Ersetzt Ausgabe: | Verteilt an: |
|--|-----------|------------------|---------------|
| P. Ullrich 20.09.2013 | | 01.10.2009 | P. Ullrich |
| Datei: UP PLM SiCA Junior Cup and KS Occlusal Brushes 2013 | | | Seite 3 von 4 |

Sterilisation and Instructions for Use

validation and monitoring of the process. Any deviation from these instructions should be properly evaluated for effectiveness and potential adverse results.

| Erstellt: | Freigabe: | Ersetzt Ausgabe: | Verteilt an: |
|--|-----------|------------------|---------------|
| P. Ullrich 20.09.2013 | | 01.10.2009 | P. Ullrich |
| Datei: UP PLM SiCA Junior Cup and KS Occlusal Brushes 2013 | | | Seite 4 von 4 |