

Safety, Usage and Hygiene Recommendations for Rotating Instruments As of 06/2019

BUSCH & CO. GmbH &Co.KG Unterkaltenbach 17-27 51766 Engelskirchen GERMANY

Safety recommendations

- Until they are first used, rotating instruments should be kept in their original packaging, and protected from dust and moisture, at room
- temperature.

 Always keep the packaging (also during the active usage period) so that the instruments are traceable if required.
- Always use fully functioning, correctly serviced and maintained as well as cleaned turbine drives as well as hand-held and angle-piece drives.
- Insert the instruments as deeply as possible. Check for firm seating.
- Use respiratory and/or eye protection and an extraction system.
 Before starting to work on the workpiece, bring the
- instruments up to operating speed and make sure that they are running concentrically.
- Observe the maximum speed (as indicated on all BUSCH) Observe the maximum speed as inducted on an access, packaging). Risk of overheating and injury.

 Make sure that the instruments don't get jammed or levered.

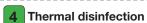
 Do not exceed a contact pressure of 0.3 to 2.0 N. (Risk of
- breakage and latrogenic injuries in the working space and danger of heterotropic ossification after overheating/burning.) Only use the instruments in accordance with their intended use
- Failure to comply with or adhere to the following hygiene recommendations can lead to transmission of pathogens
- If possible, use the entire length of the working part in order to avoid point overheating, e.g. of the tips (resulting excessive mechanical stress and local overheating).
- Make sure that there is sufficient water cooling to avoid unwanted heat development (overheating). For practice, this means a minimum cooling flow of 50 ml per minute
- ensure a minimum. FG instruments with a total length of more than 22 mm or a head diameter more than 2 mm might require additional cooling.
- Surgical instruments with a long shaft might require additional
 - Bent or non-concentrically running instruments or instruments with damaged or worn working parts must be rejected and disposed of in order to avoid injury or overheating through friction caused by blunt instruments.

Hygiene recommendations









Area of application: Rotating instruments made of steel, carbide, ceramic or diamond as well as polishers, abrasive tools and brushes that are intended for the application on humanas. The instruments are delivered non-sterile. Before they are used for the first time as well as after each use, they must be disinfected or cleaned and disinfected or, if required, sterilised. Grinding caps and cap mandrels have to be disinfected and sterilized unmounted for hygienic and technical reasons.

Restrictions for the processing of resterilisable instruments: Brushes for prophylaxis are single-use products because it cannot be guaranteed that the brushes can be cleaned entirely free from residue. For non-rust-free instruments, disinfectants and cleaning agents with corrosion protection must be used. Non-rust-free instruments are not suitable for steam sterilisation. The product service life is determined by wear and damage caused by the instruments' use. Therefore, specific details regarding the number of processing runs cannot be provided. Never use hydrogen peroxide (H₂Q₂) for disinfection of the instruments because the risk of damage to the material cannot be excluded.

pre-cleaning is needed for the first use of brand-new instruments Preparation (pre-cleaning) on site after use

- · Wear protective clothing and mouth, nose and eye protection as well as perforation-proof gloves
- Remove all coarse contamination (e.g. blood, tissue, composites, cements) with cellulose swabs <u>immediately</u> after treatment.
 Place the used instruments on a tray (for a maximum period of 1 hour).
- Place the instruments in a covered container (free of bubbles) for pre-cleaning/pre-disinfection.
- Use an aldehyde-free and alcohol-free alkaline cleaning and disinfection solution with corrosion protection (e.g. BIP forte eco, 4%)
- an alkaline enzymatic cleaning agent (e.g. AlproZyme, ALPRO MEDICAL GMBH; immersion time: 5-15 minutes, max. 1 workday)
- · Hand the instruments over in the cleaning/disinfection bath and keep them in the bath until the subsequent main cleaning process

CLEANING, DISINFECTION and CLEANLINESS CHECK Type of conditioning: non-protein-fixating

Machine processed thermal cleaning/disinfection unit acc. to EN/ISO 15883 (thermal disinfector) at a minimum temperature of 90°C and for a holding time of 5 minutes

- After having removed the instruments from the cleaning/disinfection bath rinse them with clean running water.
- Then place the instruments in a stand separated and secured in their positions - e.g. in the BUSCH STERI-SAFE wave instrument stand. If you use the STERI-SAFE wave, make sure that the biggest opening on the long side is aligned so that it is nearest to the main direction of the cleaning agent flow.
- Always observe the instructions of the manufacturers of the RDG and the employed cleaning and neutralisation agents.
- Only use CE-marked validated cleaning agents (e.g. Chemische Fabrik Dr. Weigert, Hamburg, neodisher MediClean forte).
- Observe any potential material incompatibilities (e.g. do NOT include instruments made of non-rust-proof steel).
- · Make sure that the instruments are sufficiently dried
- Working parts of carbide instruments might be corroded in the RDG. We recommend that you use the BUSCH STERI-SAFE

instrument stands with a safety strap which will prevent the instruments from falling out of the stand.

Manually (by hand)

with a hard. fine-bristle plastic brush under clean running tap



Ultrasonic-based cleaning

success cannot be assessed with sufficient certainty (e.g. because of cavities or inaccessible spaces that cannot be inspected)

Place the instruments in the immersion bath fully and free from air bubbles. The immersion periods, concentrations and usage periods which are specified by the manufacturer of the cleaning agent and disinfectant must be strictly observed in order to avoid damage to the material. Check the performance of the ultrasound unit and service the unit in regular intervals.

Disinfectants for the instrument disinfection of rotating instruments must have a CE mark with a 4-digit number. Only select agents which are expressly recommended as suitable by the manufacturer for the disinfection of rotating instruments of the groups of the employed instrument types (steel or carbide or diamond or abrasive tools or polishers/brushes) (e.g. **BIB forte eco** ALPRO MEDICAL GMBH / alkaline, aldehyde-free and alcohol-free / 3.0% / 10 minutes).

Provided that the instructions for use by the disinfectant manufacturers and the recommendations given here are correctly observed, up until now we are unaware of any material incompatibilities as result of the use of CE-marked instrument disinfectants. Replace contaminated ultrasonic baths in due time. Do not heat the ultrasound bath above 45°C (risk of protein fixation) In order to avoid any damage to the instruments, when using **ultrasonic procedu** ideally the instruments should not touch each other or other hard material surface

(e.g. placed in the BUSCH STERI-SAFE stand).

Rinsing (under clean running water)

Drying ideally with clean dry compressed air, and alternatively with dry clean cellulose cloths

Visual inspection of the instrument for damage, wear and residual contamination (adhesions which haven't been cleaned). Aid: magnifying glass with 6-fold to 8-fold magnification. Instruments with cavities or inaccessible spaces must be cleaned particularly thoroughly and checked for cleanliness with great care

Disposal

Instrument is damaged or worn or cannot be cleaned?

STERILISATION

If classified as

The sterilisation

well as having the necessary technical knowledge and

may only be may only be carried out by personnel who are suitably trained and have sufficient experience as

Invasive application Critical medical devices A and B

Instruments which penetrate the skin or mucosa and come into contact with blood, internal tissues or organs including wounds.

Steam sterilisation using the vacuum procedure (unit according to EN 13060, validated processes)

Class-S steriliser or class-B sterilise

Critical B: It was not possible to immediately assess the cleaning success (e.g. due to cavities, inaccessible

The cleaning success was assessed as positive

Critical A:

Class-B steriliser

with fractionated pre-vacuum system and continuous monitoring through simulation testing (Helix test).

Sterilisation temperature 134°C / holding time 5 minutes (full cycle) Minimum drying time 10 minutes / Observe the limits of the ingredients for drinking water and steam condensate according to EN 13060. / Observe the maximum steriliser load. / Observe the steriliser manufacturer's specifications.

Instruments packaged and recontamination-protected in demonstrably suitable sterile barrier systems, dental cassettes or containers.

Observe compliance of devices and systems with the standard DIN EN ISO 11607-1 and with the corresponding parts in the standards series DIN EN 868.

Release given after sterilisation has been successfully completed

Documented release.

STORAGE: Provision for use or storage in packed condition and in closed cabinets The storage of the sterilised or disinfected instruments must e in a manner that they will continue to stay free of germs.

Non-invasive or cosmetic application

Semi-critical medical devices A and B

Semi-critical: Instruments which come into contact with the mucosa or with pathologically changed skin but which don't penetrate it.

CAUTION: Even if there is only a low risk of injury, skin penetration or contact with blood, the **critical** A or B assessment must be

adopted and the instruments must be STERILISED! > 3



THERMAL DISINFECTION 4

Was the cleaning method combined with thermal disinfection (validated automated, thermal cleaning/disinfection device RDG 93°C - thermodisinfector - according to EN/ISO 15883 at not less than 90°C and a dwell time of 5 minutes?

Thermal disinfection

Not suitable for polishers and brushes!

- Temperature 180°C
- Minimum holding time 30 minutes

180 °C 333

in suitable stands (e.g. BUSCH STERI-SAFE) or sieve trays

Thermal disinfection in the steam steriliser - Temperature 121°C

- Holding time 15 minutes

- Temperature 134°C - Holding time 3 minutes

unpacked

in suitable stands (e.g. BUSCH STERI-SAFE) or sieve trays

STORAGE: Provision for use or storage in a manner that the instruments are protected

Manufacturer information for the processing of resterilisable medical devices according to DIN EN ISO 17664:2018 as well as recommendation by Robert Koch Institute (KRINKO2012)



Safety, Usage and Hygiene Recommendations for Rotating Instruments As of 06/2019

Symbols



Ultrasonic bath



Washer-desinfector for thermal disinfection



sterilizable in steam sterilizer (autoclave) at the specified temperature



sterilizable in a dry heat sterilizer operating at the temperature specified



Disinfectant for manual instrumens and for rotary instruments



Packaging unit



Reference number



Lot number/batch number



Consult instructions for use



Do not reuse



Maximum permitted rotation speed [min⁻¹]



Manufacturer