

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
- 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 the dental 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 cooling.
- 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



2 Cleaning

3 Sterilisation

Thermal disinfection

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 (H₂O₂) 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 immediately 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.

2

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 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.

 \prod

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

This method is recommended especially for instruments whose 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 control 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 a 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 procedures**, ideally the instruments should not touch each other or other hard material surfaces (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 cleanling

Disposal

Instrument is damaged

GmbH & Co. KG 06/2019

Busch & CO.

134 °C

3

Invasive application

STERILISATION 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)

If classified as medical device critical B:

Critical A: The cleaning success was assessed as positive Critical B: It was not possible to immediately assess the

cleaning success (e.g. due

to cavities, inaccessible

(simplified pre-vacuum) or class-B steriliser

Class-S steriliser

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

carried out by personnel who are suitably trained and have sufficient experience as well as having the necessary technical knowledge and skills

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

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!



THERMAL DISINFECTION 1

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

Thermal disinfection in the hot-air steriliser

Not suitable for polishers and brushes!

Minimum holding time 30 minutes

180 °C **\$\$\$**

n 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

Instrument usage according to the intended use

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

Version: 19.01.2022



Hygienische Aufbereitung /hygienic processing/traitement hygiénique/preparación hygiénica



Ultraschallbad Ultrasonic bath Bain à ultrasons Baño de ultrasonidos



Reinigungs-/Desinfektionsgerät für die thermische Desinfektion

Washer-disinfector for thermal disinfection Laveur désinfecteur pour la désinfection thermique Termodesinfectadora para la desinfección termica



Desinfektionsmittel für Handinstrumente und rotierende Instrumente
Disinfectant for manual instruments and for rotary instruments
Désinfectant pour instruments à main et instruments rotatifs
Desinfectante para instrumentos de mano e instrumentos rotativos



Sterilisierbar im Dampfsterilisator (Autoklav) bei der angegebenen Temperatur Sterilizable in steam sterilizer (autoclave) at the specified temperature Stérilisable dans un stérilisateur à vapeur d'eau (autoclave) à la température spécifiée Esterilisable en esterilizador de vapor (autoclave) a la termperatura especificada



Sterilisierbar im Heißluftsterilisator bei der angegebenen Temperatur Sterilizable in a dry heat sterilizer operating at the temperature specified Stérilisables dans un stérilisatuer à air chaud à la termpérature spécifée Esterilizable en un estesterilizador de aire caliente a la temperatura especificada

Produktetikett/product label/étiquette de produit/etiquetas de los productos



Einmalige Produktkennung Unique device identifier Identifiant unique des dispositifs Identificador único del producto



CE-Symbol CE-mark Marquage CE Marcado CE



Medizinprodukt Medical device Dispositif médical Producto sanitario



Fertigungslos-Nummer, Charge LOT number/batch number Numéro de lot Número de lote de producción



Gebrauchsanweisung beachten Consult instructions for use Consulter le manuel d'utilisation Consultar las instrucciones de uso



Enthält gefährliche Substanzen Contains hazardous substances Contient des substances dangereuses Contiene sustancias peligrosas



Herstellungsdatum Date of manufacture Date de fabrication Fecha de fabricación



Maximal zulässige Drehzahl [min⁻¹] Maximum permitted rotation speed [min⁻¹] Vitesse de rotation admissable max. [min⁻¹] Velocidad de rotación máxima admisible [min⁻¹]



Nicht wiederverwenden Do not reuse Ne pas réutiliser No reutilizar



Referenznummer Reference number Numéro de référence Número de referencia



Hersteller Manufacturer Fabricant Fabricante



Bevollmächtigter in xx
CH = Schweiz
UK = Vereinigtes Königreich
Authorized representive in xx
CH = Switzerland
UK = United Kingdom
Mandataire dans I' xx
CH = Suisse
UK = Royaume-Uni
Representante autorizado en xx
CH = Suiza
UK = Reino Unido