Storage, Cleaning and Sterilization IFU

Indications For Use / General Information

A carbide bur is an invasive device intended to cut hard structures in the mouth, such as teeth or bone. It is also intended to cut hard metals, plastics, porcelains, and similar materials intended for use in the fabrication of dental devices. A diamond bur is an invasive device intended to smooth tooth surfaces during the fitting of crowns or bridges. The device consists of a shaft which is inserted into a handpiece and a head which has diamond chips imbedded into it. Rotation of the diamond instrument provides an abrasive action when it contacts a tooth. An endodontic file is an invasive device intended to treat patients with pulpitis and pulp necrosis. The device is used to probe, shape, extract, and fill conventional root canals. Clean and sterilize non-sterile instruments in accordance with the validated procedures provided below prior to first use and prior to each reuse.

Cleaning and Sterilization Instructions

Scope

These instructions are applicable to all Ohio Forge rotary dental instruments (carbide burs, diamonds instruments, and endodontic files). They are applicable before initial use, and after each subsequent use. Rotary dental instruments are provided mechanically clean, but not sterile (unless labeled "STERILE"). It is the user's responsibility to sterilize instruments before the first use and before each additional use. Instruments indicated as non-sterile, single use should be cleaned and sterilized following these guidelines before the initial use only and then properly discarded after the initial use.

Warnings

1. Do not use cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel. Cleaning agents with neutral pH are recommended.
2. Do not use Cold Sterilizing Methods for the sterilization of rotary dental instruments. These agents often contain strong oxidizing chemicals that may dull or weaken rotary dental instruments.
3. Used rotary instruments, damaged sterile packaging and unintentional open packaging shall be considered contaminated. Follow appropriate precautions by utilizing this recommended cleaning and sterilization guideline.
4. Always wear personal protective equipment (PPE) including gloves, mask, and eye protection. The physician must determine if specific patient risks are present and utilize specific controls, they deem necessary to address these specific patient risks.

Reprocessing Concerns

The product end of life is determined by wear and damage in use. Rotary dental instruments should be inspected for defects (i.e. broken tips, broken sections on flutes, etc.) during the cleaning process (under magnification).

Delay in reprocessing must be kept to a minimum (1 hour maximum) to avoid contaminants drying thereby making cleaning more difficult.

Containment/ Transportation

Rotary dental instruments can be transported wet or dry and should be protected from damage. If transported wet there is an increased chance of staining or corrosion. Prolonged storage in disinfectant solutions may result in degradation of the product and must be avoided.

Manual Cleaning Procedure

If hand cleaning is the only available option, rotary dental instruments should be cleaned in a sink reserved for cleaning instruments.

Rinse the instrument under cool running water for at least one (1) minute to remove excess contamination.

Prepare a fresh bath of neutral-pH cleaning solution. Follow the cleaning agent's manufacturer's instructions. Immerse the instrument and soak for 10-30 minutes.

After soaking, and keeping it immersed, brush the full circumference and length of the product thoroughly away from the body using the neutral cleaning agent for at least one (1) minute. Care should be taken to avoid spreading contaminants by spraying or splashing during the brushing process. Use of a soft bristled brush is recommended; wire brushes should only be used with caution as brass particles may result in galvanic corrosion and steel particles may cause discolouration of stainless steel.

Special care should be taken to clean crevices and other hard-to-reach areas thoroughly. Visually inspect to confirm the removal of debris (under magnification). Repeat the cycle if needed.

Thoroughly rinse the instrument under running warm water for at least one (1) minute until visibly clean and any remaining detergent has been removed.

Dry the instrument using a lint free cloth or filtered pressurized air.

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Automated Cleaning Procedure

Rinse the articles under running water to remove excess contamination. Transfer the articles into the automatic washer for processing.

Alkaline Detergent

STAGE	CYCLE TIME (MINUTES)	TEMPERATURE	DETERGENT TYPE AND CONCENTRATION
Pre-wash	2:00	Cold tap water	N/A
Wash 1	5:00	43°C Tap water	Alkaline detergent prepared per detergent and washing equipment manufacturer's recommendations
Neutralization Wash	5:00	43°C Tap water	Neutralizing agent prepared per detergent and washing equipment manufacturer's recommendations
Rinse 1	1:00	60°C Tap water	N/A
Thermal Rinse	5:00	90°C DI water	N/A
Dry Time	5:00	115°C	N/A

Enzymatic Detergent

STAGE	CYCLE TIME (MINUTES)	TEMPERATURE	DETERGENT TYPE AND CONCENTRATION
Pre-wash	2:00	Cold tap water	N/A
Wash 1	5:00	40-60°C Tap water	Enzymatic detergent prepared per detergent and washing equipment manufacturer's recommendations
Rinse 1	1:00	60°C Tap water	N/A
Thermal Rinse	5:00	90°C DI water	N/A
Dry Time	5:00	115°C	N/A

DI – deionized water

Visually inspect to confirm the removal of debris (under magnification). Repeat the cycle if needed.

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Inspection Testing

1. Carefully inspect each instrument to ensure that all debris has been removed (under magnification).
2. Visually inspect the instrument for damage/ wear (under magnification). that would prevent proper operation.
   - Do not use if the tip is broken.
   - Do not use if there is a broken section of a flute.
   - Do not use if there is evidence of corrosion.
   - Do not use if there is evidence of excessive wear of tool (i.e dull)

Sterilization

Seal instrument in a sterilization pouch. Use the following cycle for steam sterilization.

Cycle Type	Minimum Sterilization Exposure Time (minutes)	Minimum Sterilization Exposure Temperature (minutes)	Minimum Dry Time (minutes)
Gravity	30	121°C (250°F)	30
Pre-Vacuum (4 Pulses)	4	132°C (269°F)	30
Pre-Vacuum (4 Pulses)	3	134°C (273°F)	30

Ensure that the sterilizer manufacturer's maximum load is not exceeded. Ensure the validated minimum dry time has been achieved to ensure that the devices will not be left wet. Failure to achieve the minimum dry time may cause moisture to remain on the instruments that could result in corrosion.

Storage

After sterilization, store instruments in a dry, clean, and ambient temperature environment in the sterilization pouch until required. Please note the shelf-life of the sterilization pouch as per the manufacturer's validated specifications.

Additional Information

These processes have been validated as being capable of preparing Ohio Forge rotary dental instruments for initial use and/or reuse. Any deviation from these instructions must be properly validated for effectiveness and prevention of potential adverse results.

Validation

These processes have been validated on maxill Ohio Forge rotary dental instruments. Following these instructions along with the instructions for the cleaning agents and equipment utilized remains the responsibility of the user. Proper steps are to be taken to ensure all equipment is operating safely and properly in accordance with manufacturer's guidelines and specifications. Any deviation from these guidelines and specifications requires validation prior to use and subsequent monitoring for effectiveness and potential risks. Results of Validation of this cleaning and sterilization process are documented and maintained by maxill.

LOT Batch Code

Operating Instructions

Do not use if package is damaged

Caution

REF Device Identifier

Use by Date

STERILE R Sterilized using irradiation

Recyclable

Do not re-use

maxill inc.
www.maxill.com 1-800-268-8633

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